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Food·Drug·Cosmetic Law Journal

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1960 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc.—Papers by Government Officials and by Industry Representatives at the Sessions on November 28

See Table of Contents for Articles in This Issue

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

The 1960 Joint National Conference of the Food and Drug Administration and The Food Law Institute, Inc., was held on November 28 and 29, 1960, in the auditorium of the United States Department of Health, Education, and Welfare in Washington, D. C. Food additives, color additives and other problems under the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Labeling Act were discussed.

The following organizations cooperated in the conference: American Medical Association, Association of Food and Drug Officials of the United States, The Food Protection Committee of the National Research Council, The Food Additives Committee of the Manufacturing Chemists' Association, The Food Additives Committee of the Institute of Food Technologists, Grocery Manufacturers of America, Inc., The Nutrition Foundation, Inc., and The Packaging Institute, Inc.

This issue of the FOOD DRUG COSMETIC LAW JOURNAL is devoted to the papers presented at the morning and afternoon sessions on November 28. Moderator of the opening session on November 28 was **Commissioner George P. Larrick,** whose introductory remarks followed welcoming statements by Arthur S. Flemming, Secretary of Health, Education, and Welfare, and William T. Brady, chairman of the board of trustees of The Food Law Institute.

Mrs. Carla S. Williams, of the Bureau of Program Planning and Appraisal of the Food and Drug Administration, presented the first paper, a description of the FDA's consumer consultant program. "Consumer interest is at its most vigorous in years," she points out, stating that it has undergone a resurgence not seen since the early 1930's and the depression years. Activities of the program will be stepped up in the coming months.

J. Kenneth Kirk, Assistant to the Commissioner of Food and Drugs, told the conference what the score card shows for food additives at this time as he discussed developments in this field, while **Franklin D. Clark,** Assistant to the Deputy Commissioner of Food and Drugs, discussed color additives. Another representative of the FDA, **Winton B. Rankin,** who is Assistant to the Commissioner, spoke on the Federal Hazardous Substances Labeling Act.

Dr. Bernard L. Oser presided over the industry afternoon session of the conference on November 28. He is the president of Food and Drug Research Laboratories and is well known to the readers of this JOURNAL.

"Problems Involved with the Administration of the Food-Additives Amendment" was the topic of **Dr. Richard S. Gordon,** director of research, Agricultural Chemicals Division, Monsanto

Chemical Company. He addressed the conference as a member of the Food Additives Committee of the Manufacturing Chemists' Association, Inc.

The secretary of the Labels and Precautionary Information Committee of the Manufacturing Chemists' Association, Inc., **James D. Kittelton,** presented industry's views on the Federal Hazardous Substances Labeling Act to the conference, after reviewing some of the progressive steps which the chemical industry voluntarily took in the field of precautionary labeling before adoption of the act.

Dr. Margaret Ives discussed the impact of the new food law amendment on research in food technology. She is senior research toxicologist at the American Can Company Research Center in Barrington, Illinois.

The work of the Scientific Advisory Committee and the administration of color additives were described by **Joseph D. Becker,** assistant to the director of the Legal Department of Allied Chemical Corporation.

Dr. Robert N. Johnson, chief chemist of The Kroger Company, delivered an address on the relation of the food-additives amendment to packaging materials. He made an inventory of the status of the various programs in his field as they stand at the present time, concluding that "There is general optimism regarding the progress and eventual results of the various programs for compliance with the law of present packaging material. On the other hand, there is a very definite negative note as to the effect of the law on research and development of new materials."

The assistant to the director of the Research and Development Division of the National Dairy Products Corporation in Glenview, Illinois, **Dr. B. E. Ellickson,** concluded the afternoon session with a discussion of additive labeling.

Franklin M. Depew, president of The Food Law Institute, visited a number of food and drug officials of international organizations and of European countries following the British Pure Food Centenary, which was held in London last September and which he attended as vice president of honour. His report of the visits concludes this issue of the JOURNAL.

AOAC Wiley Award Nominations

Nominations Invited for AOAC's Harvey W. Wiley Award.—Dr. C. O. Willits, president of the Association of Official Agricultural Chemists, announced that nominations are now being accepted for the fifth AOAC Harvey W. Wiley Award for Achievement in Analytical Methods. This award of $500 will be given to the scientist or group of scientists who have made outstanding contributions to the development of analytical methods for foods, drugs, cosmetics, feeds, fertilizers and pesticides or for use in general analytical chemistry. These are the fields of interest to the AOAC which are encompassed in its publication, *Official Methods of Analysis,* the primary laboratory manual of regulatory chemists and research workers in agriculture in the United States and throughout the world.

Mr. Jonas Carol, of the Food and Drug Administration, won the 1960 award for his outstanding contributions in advancing the frontiers of the analytical methodology of drugs.

Nominations must be submitted to the secretary of the association by April 1, 1961. Nominees need not be members of the association. Further information about the award may be obtained from the secretary, William Horwitz, Box 540, Benjamin Franklin Station, Washington 4, D. C.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Food Seizures in November.—A total of 801.5 tons of contaminated foods was seized in 76 court actions in the month of November. The largest number of actions was taken against grain and grain products which were contaminated by rodents and insects. A total of 168 tons of grain was seized in 22 of the 76 court actions.

The second largest category of food involved in seizure proceedings was frozen eggs. A total of 65 tons containing decomposed eggs were seized; 60 tons were involved in one action.

Almost 491 tons of the 801.5-ton total of food seized became contaminated in warehouses while held for sale after shipment in interstate commerce.

Drug and Device Seizures.—Twenty federal court actions were taken against drugs and devices in the month of November. The charge of false and misleading therapeutic claims was made in 15 of the actions; other actions involved four substandard products and one case of amphetamines sold without labeling or the required prescription.

Voluntary Actions by Industry to Improve Consumer Protection.—Over 839 tons of adulterated food were destroyed or converted to animal feed by industries voluntarily seeking to avoid violations of the law.

More than 50 companies voluntarily destroyed batches of root beer or root beer syrup which had been made with safrol or oil of sassafras, a flavoring agent recently found to be a hepatic carcinogen. As a result of the scientific find, the Food and Drug Administration acted to stop further use of safrole or oil of sassafras in foods or beverages.

The drug industry voluntarily destroyed $4,067 worth of adulterated drugs in seven separate actions. The largest of these involved the destruction of 234,000 tablets representing ten different drugs. Inspection showed that the drugs were old, varying in age from three to 19 years. Some had obsolete labeling; others appeared to have undergone deterioration.

Voluntary plant improvements totaled $1,229,700 in value in 23 actions. Over $1,100,000 of the total amount was used in expansion and construction of five buildings to eliminate insanitary conditions found upon inspection of previous facilities.

Protecting Consumer in "Weightlessness" Products Field.—The public's current preoccupation with the reshaping of the human figure—via a myriad of new liquid formula diets—is also keeping the Food and Drug Administration's inspectors on the jump.

Most manufacturers of the weightlessness preparations have carefully warned the dieters to consult their doctors. Also for dieters' protection, the FDA requires that labels on the can must give a complete run-down on the ingredients in the liquids.

Even so, the FDA inspectors have been alerted to maintain a close sur-

veillance to guard against possible fraudulent promotions and products which may not, in fact, be adequate to accomplish the claims of the makers.

There have been two FDA actions taken against liquid diet preparations, both in the Washington, D. C., area. The FDA seized shipments of two products which included some 6,335 pounds of the food supplements awaiting delivery to impatient buyers, valued at $7,500.

In the larger of the two seizures, the FDA found that a "900 calorie food concentrate" (840 boxes containing 5,040 pounds of chocolate-flavored mix valued at $5,040) had 48 per cent less protein than its label declared and 22 per cent more fat. The same product with vanilla flavor (160 cases containing 960 pounds of mix) lacked 21 per cent of the declared amount of protein and had an excess of 13 per cent of the declared amount of fat. Such a product obviously is not a reliable source of measured and balanced nutrition, the FDA said.

In the second case the government charged that another liquid diet was misbranded by false nutritional claims. An accompanying circular claimed that one serving was equal to a complete meal including a six-inch square of steak, and that it would enable adults, children and infants to either gain, maintain or lose weight, depending on the individual's choice.

The FDA also charged that circulars and placards referring to the product as a "food concentrate" did not clearly reveal that it must be added to milk in order to have the nutritional properties claimed for it. Adulteration was charged, because fat and carbohydrates had been substituted for some of the claimed amount of protein. A total of 335 pounds of powdered mix was seized, valued at $1,500.

With the number of mix-at-home preparations continually on the upswing, and a trend to ready-mixed cans and even to soda-fountain dispensing, the FDA inspectors are busier than ever in their effort to make certain that consumers get what they pay for.

Heavy Penalties Imposed on Illegal Peddlers of Amphetamines. — Heavy penalties were imposed by federal judges in November in three cases against persons charged with the illegal sale of amphetamine pills, popularly known as "bennies," at their truck-stop establishments. These actions are the outcome of a series of Food and Drug Administration investigations made last fall on the illegal sale of amphetamines to truck drivers. Over 55 cases have been developed during the year as a result of these investigations, the FDA said.

Cancer Clinic Closed by Court.— The Taylor Clinic, dispenser of the Hoxsey treatment, a worthless cancer remedy, has completed the final step required by a federal court injunction prohibiting distribution of the treatment. The injunction specified that letters be sent to 10,270 patients notifying them that the treatment is no longer available.

Dr. Harry R. Taylor wrote patients that the clinic doctors and employees "could be held in criminal contempt of a Federal Court for using or delivering the Hoxsey treatment to anyone at the Taylor Clinic or elsewhere."

The injunction was issued at Dallas, Texas, in September, 1960, by United States District Judge J. E. Estes. It culminated ten years of almost continuous litigation by the Food and Drug Administration in efforts to stop the clinic from dispensing medicine which the clinic claimed would cure cancer without surgery or radiation. The Food and Drug Administration had proved by scientific tests and research that the medicine was worthless for the treatment of cancer.

Prior to 1957 the clinic was owned and operated by Harry M. Hoxsey,

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Journal

1960 Joint National Conference—FDA-FLI

Statement

By GEORGE P. LARRICK

This Was the Statement Made by Mr. Larrick, Commissioner of Food and Drugs, Before the First Session of the Food and Drug Administration-Food Law Institute Conference Held in Washington, D. C., November 28.

I AM PLEASED to add the sincere welcome of the Food and Drug Administration to that of the Secretary of Health, Education, and Welfare as we open this Fourth Annual Food and Drug Administration—Food Law Institute Conference. The worth of such a meeting to consumer organizations, to industry, to the legal profession and to the Food and Drug Administration has been amply demonstrated in previous years.

Let us briefly review some of the more important advances that have been and are being made in the protection of consumers of foods, drugs and cosmetics. You are well aware of the recommendations made by the Citizens Advisory Committee in 1955 after it studied our operations at the request of Secretary Oveta Culp Hobby. Since then, the Congress has appropriated money to construct the shell of a new headquarters and laboratory building to house our Washington operations. Bids have already been received on construction of the building, and we anticipate that the actual work will get underway in the near future. There is every reason to believe that

the Congress next year will appropriate the additional funds necessary to equip the building. Then for the first time in many years we will have the bulk of our Washington activities housed under one roof, and you and we will begin to benefit from the increase in efficiency that such an arrangement will permit.

Renovation of Offices and Laboratories

Meanwhile, our field offices and laboratories are being renovated so that they, too, can do a better job of protecting consumers. Some of you who have visited our districts have mentioned the crowding and the antiquated equipment that are in evidence. Some of the field units already have been improved. We have authorization to modernize more than one half of them, and by the end of calendar year 1962 we hope to have ten of the 18 districts modernized and to have authority to bring four more up-to-date.

Plans for Animal Research Laboratory

Money has been made available to plan for a special animal research laboratory. If Congress approved the plans which are now being drawn, we should have the building constructed and be using it sometime during calendar year 1962. This will permit the rapidly increasing animal testing work to go forward in modern quarters where the animals can be housed in a manner consistent with current standards of scientific research and humanitarianism.

Funds to Increase Staff

The Congress has granted funds to increase our staff at roughly the minimum rate recommended by the Citizens Advisory Committee. We have been able to recruit good personnel to fill our vacancies. I know there was some question in some people's minds in 1955 as to whether we could possibly get as many new employees as were contemplated by the Citizens Advisory Committee, and if we did, as to whether we could possibly train them adequately. It is now evident that the answer is "yes" on both counts. One of the most inspiring developments of recent years is to go out to our field offices, meet the many newcomers, and see the interest and enthusiasm they are bringing to the Food and Drug Administration. We have a vigorous training program that is making well-qualified inspectors and analysts out of new employees in a minimum of time. I feel sure that each

of you shares our thankfulness that we are able to do a better job of preparing to deal with the problems of modern technology.

Improvement in Internal Management

We have already made great strides in improving the programming, planning and internal management of the Food and Drug Administration as recommended by the Citizens Advisory Committee. The shift to a bureau type of organization, the strengthening of our Bureau of Program Planning and Appraisal, and other steps that you have observed in the past few years are contributing factors. And our further growth in this area is being pressed vigorously. For example, we are in the process of acquiring electronic data-processing equipment. This will help compile and analyze the tremendous quantities of data that accumulate in the administration of laws affecting over $70 billion worth of foods, drugs and cosmetics.

Division of Public Information

Also, as recommended by the Citizens Advisory Committee, our educational and informational programs are being expanded. A new division—the Division of Public Information—has been established and has served a real need. And about a year ago we appointed Mrs. Carla S. Williams as the director of our consumer consultant program, which is designed to keep the Food and Drug Administration better informed as to the needs and wishes of consumers with respect to our activities.

In addition to funds, new personnel, new equipment and new space, the legislative authority under which we accomplish our consumer protection has been improved in the recent past.

Problems Encountered

We have had some difficulties during the past year, too. You are acquainted with the developments after a Congressional committee determined, by subpoenaing his records, that one of our key employees had been engaged in activities that were not compatible with his government job. Many people have since made searching inquiries into the activities of the FDA.

One group, the Special Investigative Unit appointed by the Secretary to investigate the integrity of employee actions in the FDA, has rendered a preliminary report. This expresses the unit's judgment

that on the basis of a mass of evidence "there are no present employees of FDA whose sources of personal income are incompatible with their Government employment." Thus the group confirms our long-standing confidence in the integrity of our employees.

Committee of Medical Experts

Another group, a committee of outstanding medical experts, was appointed by the National Academy of Sciences at Secretary Flemming's request to look into the soundness of medical and other scientific decisions we have made with respect to new drugs and antibiotics. This committee found the decisions it reviewed acceptable.

Limited Facilities

But its investigation revealed another thing that we all recognize: The job confronting us is too big to be handled properly with the limited facilities that we have available. The committee called attention to this fact and recommended a number of actions that it thought should be taken to correct weaknesses it observed in the existing law and current staffing and budgetary support of the FDA. It is true that modern technology and newer social developments continue to outstrip the abilities of the Food and Drug Administration to perform fully its intended purpose.

We do not have facilities to safeguard the food and drug supply adequately from contamination with radioactivity. We do not even have facilities to determine on a statistically sound basis whether the amount of radioactivity now occurring in food constitutes a near-range or a long-range threat to the public health.

Limited Authority

We do not have the authority to require a cosmetic to be tested for safety and proved safe before it is placed on the market. Nor do we have authority to require a new therapeutic device to be safe before it is marketed commercially to physicians or laymen.

The law does not require a drug manufacturer to establish the therapeutic value of a drug or device before he places it on the market.

The law does not require a drug manufacturer to have adequate manufacturing and laboratory controls before he engages in interstate commerce.

The law does not require a number of important antibiotic drugs to pass through the certification system that has proved so worthwhile as applied to penicillin and four other types of antibiotics.

The factory inspection provisions of the law need strengthening.

I mention these points simply to highlight the fact that while the FDA has come a long way in the past five years, it still has a long way to go before it is prepared to do the job the American public has the right to expect of it. We are encouraged by the progress of the past few years, but we are not complacent.

As a matter of fact, there have been so many dramatic developments in the past five years in our field that we believe it is time for a new Citizens Advisory Committee to look at our total operation and give us current advice on the steps that should be taken to cope with the current problems. In the coming months I will need to discuss this matter with the Secretary, and I would welcome any suggestions you have about it.

In closing, it is an inspiration to us to have so many representatives of consumer organizations and industry come from so many parts of the United States to participate in this conference. We sincerely hope that you find the meeting profitable. We earnestly solicit your frank suggestions as to methods in which we can improve our operation. **[The End]**

CANADIAN REGULATIONS STRENGTHENED

Mr. C. A. Morrell, Director of the Canadian Food and Drug Directorate, has made the following statement in regard to illicit barbiturate and amphetamine sales:

"Due to a growing illicit traffic in barbiturates and amphetamines it is necessary to strengthen the regulations under the Food and Drugs Act which control the manufacture, importation and sale of these drugs. I therefore propose to submit the following regulations to the Honourable, the Minister of National Health and Welfare.

"*C.01.048* No person shall manufacture, import or sell amphetamine and its salts or barbituric acid and its salts and derivatives which are not in combination with other drugs, unless he maintains a record, in a form and content satisfactory to the Minister, respecting the quantities of such drugs manufactured, received or sold and such records shall be maintained for a period of at least 5 years.

"*C.01.049* The provisions of C.01.048 do not apply to a practitioner."

The FDA's Consumer Consultant Program

By CARLA S. WILLIAMS

Public Opinion Molds the Law, and the FDA's Consumer Consultant Program Helps to Understand This Opinion. Mrs. Williams Is with the Bureau of Program Planning and Appraisal of the Food and Drug Administration and Presented This Paper at the FDA-FLI Conference.

I AM MOST GRATEFUL for the opportunity to discuss a subject very near and dear to my heart. As many of you may not know, I am a rather new employee of the Food and Drug Administration and so would ordinarily "shy away" from discussing any of our FDA programs before a group so senior to me in knowledge and experience.

However, despite the vast experience represented here today, and my "newness," I come before you to discuss something that perhaps even *you* do not know about the FDA—the agency you have come to know so well during these past 11 years—and that is the FDA's consumer consultant program.

I sincerely doubt if many of you know that today there are women located throughout the Food and Drug Administration's 17 field districts who are working for us *not* in administrative jobs, *not* in the laboratories, *not* out in the field as inspectors, but, rather, as part-time consultants for the Food and Drug Administration. These highly qualified women, carefully chosen for their professional background, are adding a very real contribution to the Food and Drug Administration's work, and are supporting the enforcement of food, drug and cosmetic laws by working directly with the public. In *talking* about drugs, cosmetics and food, they are giving the consuming public "food for thought," we believe, and they are finding that the public is vitally interested in—in fact, hungry for—information about foods—their facts, fallacies and fads, about drugs and devices,

about cosmetics and caustics, and about the laws behind the label, pills and packaging. And yes, we are still asked about cranberries and carcinogens, too! Before I tell you more about the consumer consultant program, I would like to go back a few years.

Background of Program

While Charles W. Crawford was Commissioner of the Food and Drug Administration he became deeply convinced that there was a very great need for the Food and Drug Administration to know better what the public was thinking about the protections it enjoyed and how well acquainted it was with the Food and Drug Administration's work—its regulatory program, its laws and its jurisdictions. He fully realized that the public was grossly uninformed in many areas: in the protections offered them and their families, in their health and in their pocketbook! Because they were uninformed, the public seemed to be apathetic or disinterested. But Mr. Crawford believed that there was tremendous latent interest which would spring to life if people knew about our problems and our programs. He realized that public interest and sentiment, properly expressed, could serve to guide the FDA in the administration of the law, and in requesting new legislation when needed. Archibald MacLeish once said—and I believe these words, paraphrased a bit, expressed very well this wise conviction of Commissioner Crawford's: "We have learned all the answers; it's the questions that we do not know. We are not wise." If I may, I'll use that quote to read this way: "The FDA has learned *most* of the answers; it's the questions that we do not know."

At any rate, Mr. Crawford's sincere belief that the consumer's opinion could be of great help to the FDA in guiding its programs along the way resulted in today's consumer consultant program.

Increase in Consumer Interest

Fortunately, this program has continued since its inception in 1953 because today Commissioner Larrick believes as deeply in the "power" of the consumer and his interest as did Mr. Crawford. In fact, only recently Commissioner Larrick stated that consumer interest is at a new peak and has undergone a resurgence not seen since the early 30's and the depression years. This feeling is clearly justified as one looks back on 1959, then through '60 and into 1961, a year which promises to be a decisive year for the consumer.

Commissioner Larrick is right. Consumer interest *is* at its most vigorous in years. We must only look around to see that in this period of greatest productivity in history, thanks to advanced technology and countless new marketing frontiers, consumer awareness is on the increase. Part of this new alertness—or arousal, if you will—may come as a result of the Blatnik Hearings in '58, the exposures of fraud and deceit which came out of the television industry in '59, and Senator Kefauver's recent hearings on monopolies and price maneuverings.

Consumer Interest Conferences

Recognizing this new acuity on the part of the public, and the need for meeting its challenge, Attorney General William Rogers called and presided at a consumer conference, held here in Washington last March, and attended by attorneys general from all over the United States. Since then, market-place frauds and deceptions have undergone further scrutiny at similar meetings called by several state attorneys general. There were held locally to include community, county and state representatives of law enforcement agencies, consumer-type organizations, and related business and industry. The most recent of these conferences—and one which I was most privileged to attend—was held in Lansing, Michigan, in September.

The AFL-CIO has an energetic and ever-growing consumer-interest movement which holds weekly meetings for its members and publishes market bulletins, health capsules, "best buy" advice and self-protection pointers.

Interestingly, the American Medical Association announced in an October 2 release that it was launching a "comprehensive study and action program" to guide the consumer in spending his health-care dollars more wisely. And the Better Business Bureau tells us that its consumer query response has doubled in recent months.

The FDA's Bureau of Program Planning and Appraisal was gratified when during this past month a Department of Agriculture representative sought advice on how to set up a comparable consultant program within its own Food Standards Branch. Though the Department of Agriculture has conducted a highly successful Home Extension Service for years, it now realizes—in watching the progress of the FDA's Consumer Consultant Program—that the consumer can

perhaps render further important assistance to it in establishing new food standards.

Federal Trade Commissioner Earl W. Kintner has more closely related that agency's program to the consumer since assuming office two years ago. He stated at the Lansing, Michigan conference that in the past year the FTC has intensified its monitoring of labeling and identification; of false claims and misrepresentations, including those made in direct mailing; and of all illegal practices foisted on the unsuspecting consumer.

We all know that there are Senate resolutions pending. One of these, sponsored by Senator Javits of New York, provides for a Select Senate Committee on Consumers; and another sponsored by Senator Kefauver, would provide for a new Department of Consumers.

Even current book sales reflect a new consumer interest—or more accurately, a new interest in the *consumer*. Some of these books are good; some are poor. But we'll hope that through exposure their readers become more perceptive consumers or, at the least, *intelligent* skeptics!

Consumerism

Vance Packard, in his recently published book, *The Wastemakers*, coins the word "consumerism"; and while the author is largely preoccupied with the problems of overcommercialism, misleading advertising and the Madison Avenue mores which are reflected in today's buying habits, perhaps we should at least be grateful to Mr. Packard for this word. For though there is much of interest to the reader—and, indeed, the book *is* thought-provoking—I personally have much more faith in the intelligence of today's consumer, and the *power* of today's consumer, than does Mr. Packard. And, I should add, so do all of us in this room this morning, for is not The Food Law Institute itself founded on the very premise of public service and public protection? Has not the Food and Drug Administration dedicated its entire effort to protection of the consumer throughout its 54-year history?

Yes, the FDA through the years has acquitted itself well. Though a low-budgeted, understaffed agency, it has relentlessly sought a record of excellence in this field. We can, indeed, hold our heads high. But does the average consumer know this? We think not. Neither

do we think that consumers know of the perplexing problems still facing us; nor do they realize how valuable it would be to have their reaction to some of the situations on which we must make decisions. Through speaking engagements before community groups, appearing on radio and television interview shows, creating and manning FDA exhibits and eventually conducting consumer survey work, these women will create a two-way flow of information between the FDA and the consumer. They will explain, on one hand, the Food and Drug Administration's regulatory programs, its laws and its jurisdictions; and, on the other hand, by tapping consumer opinion, they will determine the reactions and attitudes of the American public toward the food, drug and cosmetic products which come under the FDA's jurisdiction. In this way the consumers will have a better understanding and appreciation of the protection offered them. At the same time, their response will be helpful to the Food and Drug Administration in conducting its regulatory programs, today and in the future.

Public Opinion Response

We have had a sampling of public opinion in recent months which illustrates the potential of this largely untapped reservoir of consumer opinion in giving us administrative guidance.

For example, we have received thousands of letters on the subject of the chemicals used in the growing and processing of foods. Many of these have shown some misunderstanding of the problems confronting us. However, they were overwhelmingly in agreement on the proposition that our programs must assure the safety of the hundreds of chemicals being added to our foods.

We had another interesting reaction on an industry proposal for amendment of the standards for jams and jellies to allow the use of certain liqueurs and rum as flavoring agents. Hundreds of individuals and organizations wrote us in opposition to this proposal. The amendment never came to pass!

And you should have seen our volume of mail—and heard the public's clamor—following news stories about the way our research dogs are housed!

Then, of course, we have received a tremendous volume of inquiries about the lipstick-color situation. These leave no doubt but

that most women want their lipsticks—but also that they want the government to do whatever has to be done to make them safe.

Appraisal of Problems

This, then, is the type of information which our consumer consultant program is obtaining from consumers for the Food and Drug Administration. I am in the Bureau of Program Planning and Appraisal, which would like to compile this information and use it in the planning and as a part of the "appraisal" of the effectiveness of our regulatory programs; and we would like to build it right into new programs so they will give better consumer protection.

One of the chief obstacles in doing this heretofore has been our concern that the consumer views we were getting were not sound. We have been afraid that the consumer did not really understand *our* problems or *his own* problems, and that we were getting ill-considered or nonrepresentative views. However, through the consumer consultants, we have a mechanism for *explaining* these problems to consumers, for thorough discussion of them and for stimulating truly authoritative consumer opinion and response to the Food and Drug Administration. They are telling an accurate story about additives, giving a positive explanation about pesticides; they clarify the public's bewilderment regarding supplements; and they give instructions on the value of reading the label. They tell the "fair story," not the SCARE story! With this positive approach, then, the FDA is receiving a positive response.

Food Standards Work

One of the most obvious areas for undertaking this program is that of food standards work. We have recently tried to encourage more consumer participation in food standards making, by setting up a special consumer mailing list for proposed changes in food standards or proposed new standards. We have tried to explain to these consumers, in releases geared to consumer-level understanding, just what is involved.

But the written word is often not enough. We must *meet* with consumers and talk about these things. Only then can we be sure that we know what consumers expect in a standardized food; whether they would be deceived by a particular label statement; or whether a label is truly informative, as it is intended.

Labeling of Foods and Drugs

Another obvious program area is that of the labeling of foods. We sometimes lose lawsuits—but more often hesitate to bring them—because we are not sure what some particular labeling means to consumers.

The same applies to the labeling of vitamins and drugs. How many consumers know how to read a vitamin label intelligently? How many understand the key phrase "minimum daily requirement"? Are the wordings of directions for use and warnings on drugs understandable to the anxious mother of a sick child?

We think that consumers could undoubtedly give us many valuable suggestions on these and countless other matters.

Upsurge of Consumer Recognition

The consumer consultants provide us channels for contacting consumers, for explaining the technical aspects of a problem and, then, for "brainstorming" ideas for improving consumer protection.

So it is that the activities of our consumer consultant program will be stepped up in the coming months. In fact, where we had only 13 consultants at the time of my appointment last December, we now have 17. This means that each of the FDA's field districts has at least one consultant, and soon we will recruit a consultant for our new Dallas district.

Interestingly, Commissioner Larrick's interest in the consumer, from a federal level, is shared by several governors throughout the United States. New York was the first state to set up a consumer counsel program, which was inaugurated by Governor Averill Harriman and directed by Dr. Persia Campbell. That was in 1955, and now the idea is rapidly spreading to other states. In October of 1959 Mrs. Helen Ewing Nelson became the first consumer counsel for California; Massachusetts has just created an identical department; and Governor Orville Freeman of Minnesota has a similar recommendation now under study by the state legislature. This is true also in the States of Pennsylvania and Michigan.

So you see, consumer recognition is on the upsurge. And well it should be. Public opinion molds the law—both in its enactment and in its enforcement—and public opinion is what we seek.

[The End]

Food Additive Developments

By J. KENNETH KIRK

There Has Been a Tremendous Increase in Activity on the Part of Just About Every Industry Touched by the Food-Additives Amendment, and It Seems to the Author That This Will Result in Many More Effective Regulations for the Benefit of All Concerned. Mr. Kirk, Assistant to the Commissioner of the Food and Drug Administration, Presented This Speech at the Recent Conference of the FDA-FLI in Washington.

AT LAST YEAR'S MEETING, we discussed direct and indirect additives from the standpoint of the food-additives amendment. We had before us at that time the March 6, 1960 effective date, and expressed some concern at the many things which needed to be done under this amendment before it became fully effective. Shortly thereafter, there was a very substantial upswing in our food additives work; but this took the form principally of requests for extension of the effective date for the additional one-year period which was contemplated by the law where there could be a showing of necessity for the extensions and no undue risk to the public health during that period.

We received over 900 requests for extension, these requests covering from one to as many as 1,100 items each. Thus, for the first half of 1960, a great part of the time of our food additives people and the staff of the technical divisions of our Bureau of Biological and Physical Sciences was taken up by evaluation of these requests for extension on an item-by-item basis.

We found that we could grant most of the requests; and we have published in the *Federal Register* the extension listings covering over 3,000 different items although, of course, the great bulk of these were in the field of flavors, packaging materials and equipment components.

Since we are mentioning figures, let us see what the score card shows for food additives at this time. We have answered well over

3,000 letters. For a while, we were embarrassed that we were not able to reply to your letters in a reasonable time, although it was gratifying to see that most of those who did not get answers in a reasonable time were tolerant in the recognition that our people were doing the best they could to deal with the many demands on their time. However, we have been doing better. Currently we have less than 200 unanswered letters in this field, practically all of them being late October and November correspondence. We are still trying to improve.

We have received 265 petitions for food additive regulations. Some of these are still under consideration. We have already filed 80 of these, with notice of filing being published in the *Federal Register*.

We have issued 36 final regulations, some of which have already been amended. This fact should be especially noted by those who had some concern that a food additive regulation, once issued, would be a static document. This should also, in our opinion, suggest that if anyone is holding off on the submission of a food additive petition, to be sure that he has complete data on every possible use of his additive, it might be well to consider early submission of a petition for the items on which he is ready to go forward now, with the idea that amendments can come later.

In some of the petitions submitted and in the case of some items which have been discussed with us, the question of methodology has been a bothersome one. Certainly there has been no change whatsoever in our position that we will not issue a regulation setting tolerances for a food additive without having a good method for enforcing any such limitation as is established. We have, however, demonstrated that we are not bound to any specific method of procedure in establishing a means of enforcing this type of regulation. We believe that the polypropylene packaging material matter, which established a regulation for that substance on a specification basis, was an important breakthrough in this field. We are willing to consider any other approach which may be suggested where the ordinary chemical examination of the food has been shown to be an impractical or even impossible approach.

When one looks at the large number of items published in the extension lists and compares these with the 80 petitions already filed or even with the 265 submitted to us, the first reaction may well be that here we have an impossible task of considering petitions and issuing regulations for all of these substances prior to the March 6,

1961 effective date. While we have no illusions that all of the food additive matters will have been cleared by next March, we do not believe that the situation is as bleak as the figures may indicate. Obviously, there are some duplications in the several packaging lists. Some of the items listed have already been shown not to be food additives in that particular field. Then, both we and the industries involved have been exploring diligently the possibility of issuing a limited number of regulations, each one of which will cover a substantial number of packaging or equipment components.

The outlook for this sort of regulation seems very good; and, as you may know, we have under study a petition submitted by the Can Manufacturers Institute to deal with can liners, which exemplifies this approach. Perhaps this may be expanded to control shipping and storage tank linings as well.

Just this week we are filing a petition for a regulation covering over 800 items used in making adhesives for food packages.

Inquiries Dealing with Packaging

I spoke earlier of the correspondence we have had in this field of food additives. A substantial part of this has involved inquiries dealing with the status of various packaging and equipment items. It will be recalled that we have recommended that if there is any question of whether or not components of a particular package may migrate to specific foods with which they are in contact, such questions may be resolved through the extraction and abrasion studies following the program devised by Mr. Ramsey of our Division of Food as announced in the spring of 1959.

We remain convinced that the results of these extraction tests are valid for determining whether or not a particular packaging material, made up of one or more substances not generally recognized as safe, may be considered adequate criteria for a conclusion that the article is safe. We have repeatedly advised inquirers that under this food-additives amendment they are at liberty to make their own decisions on the question of status of items and that there is no requirement that they clear these decisions with the Food and Drug Administration. It is our view that if such a decision by a manufacturer is based on sound scientific data, there should be no occasion for any concern on his or our part. We did, however, announce—and,

in fact, make a part of our regulations—our willingness to comment on any material where a food additive question may be involved if a manufacturer desires to submit that material to us with a request that we do so. In this particular category, some manufacturers have submitted their data to us inviting our concurrence in their conclusions that their data demonstrated no food additive problem. In some instances a study of the data convinced us that the conclusion was correct, and we so notified the inquirers by letter.

We have since received complaints that some of these letters have been reproduced and used as sales pieces which competitors charged were attempts to gain economic advantages by creating the impression that the Food and Drug Administration had in this way given its endorsement to a specific firm's product. There were a few instances where it was claimed that this had worked to the detriment of other firms who had done the same type of extraction work, had made up their own minds that they had no food additive problem, but had not asked us to agree.

Certainly in answering our food additive correspondence it is not, and has not been, our intention to imply the Food and Drug Administration's endorsement of any product or to imply that some competitor's products, about which we have no knowledge, are necessarily in a different category than the item which was the subject of our letter. Perhaps the blame for the result such as I just discussed rests with us, in that our letters did not clearly express what we had intended that they should. This, therefore, has caused us to take a close look at what we have been doing in this field. Perhaps this is a good time to restate what we had intended to do and what we propose for the future.

Proposals for the Future

First, we stand ready, as in the past, to consider any proper request under the food-additives amendment which may be submitted to us by any interested party; and we promise to give our best consideration and advice as to the status of the item involved under the food-additives amendment. In the case of these packaging items, however, where a manufacturer believes he has applied appropriate tests which show that there is no migration and thus no food additive problem and he asks for our comment, we will look at the list of tests which he has made and the conclusions he has drawn from this work.

Assuming that the tests are those we regard as appropriate for the product involved, we will advise him that if the tests have been properly conducted and the findings properly evaluated, certain conclusions would be possible. These may be (1) that no food additive problem has been shown to be present or (2) that safety has or has not been demonstrated where it is clear that a regulation appears necessary to prescribe the conditions required to assume such safety. Where we can agree that no food additive problem appears to be involved, however, our reply to the inquirer must be so drafted that the "if" part of the statement is clearly stated. Further, the reply must make it plain that the Food and Drug Administration has not examined the product in question, and is not directly or indirectly endorsing it.

Thus, there should be no misunderstanding about such a letter. It cannot in any way be regarded as the equivalent of a formal regulation under the food-additives amendment. To get a formal public declaration of the fact that a particular packaging material is safe, the entire picture, including all of the data obtained on the extraction studies, should be submitted with a request that we consider it as a petition for an appropriate regulation.

Minimum of Delay

Last year, there was some justifiable criticism of delays which had resulted where we had food additive problems in connection with the filing of new-drug applications, antibiotic Form 10 applications, petitions for amendment of food standards, and pesticide tolerance petitions. We have taken definite steps to correlate our handling of submitted material in all of these categories, and believe that we are now in a position to do a better job with a minimum of delay in these fields. No doubt some of you have noticed the way in which we have worked out methods of handling combination food additive and food standard matters so as to avoid delays here.

Questions as to Extension Status of Coloring Items

Since the enactment of the color-additives amendment, we have had a number of questions as to the extension status of the coloring items such as carbon black and titanium dioxide. The effective date of the food-additives amendment was extended for these to March 6, 1961, but now that they are color additives this date has no signifi-

cance. They are provisionally listed under the color-additives amendment with the new deadline of 30 months from July 12, 1960.

Almost any discussion of the food-additives amendment results in the question of what we are going to do if March 6, 1961, arrives without enough regulations having been issued to take care of the food additives which industry believes are suitable for continued use. This usually comes up on two fronts: First, we have the question of how the limited Food and Drug Administration scientific staff is going to be able to review the heavy influx of petitions expected between now and March 6, and, second, what about the products which have been under long-term pharmacological study, the results of which can't be expected before that date? As you know, the law as it now stands does not authorize any further extensions of its effective date beyond March 6, 1961. About the best we can do now is to quote the comment of Deputy Commissioner Harvey which he made to the American Bar Association three months ago. He said:

> No policy on this question has been formulated by this Department. My own feeling is that those who have food additive problems and have just sat back and done nothing are entitled to no consideration at all from the standpoint of extensions. I do, however, believe that there may be a sound basis for legislation authorizing further extensions where long-term pharmacological studies are underway and obviously cannot be completed before next March 6. In such cases, I would think that the possibility of further extensions, where it can be demonstrated that no undue hazard to the public health would result, may be well justified.

Last year, we had occasion to comment somewhat adversely on the fact that some areas of industry had not, in our opinion, done their part in trying to get straightened away under this food-additives amendment. The picture this year is quite different. There has been a tremendous increase in activity on the part of just about every industry touched by the amendment, and it seems to us that this will result in many more effective regulations for the benefit of all concerned. Our people have offered many suggestions as to how individual problems might be solved; industry has given us many helpful suggestions. We hope that this type of approach can continue.

We do not feel that you or we have solved all the food additive problems, but we are convinced that experience to date has demonstrated the results to be obtained when there is a sincere desire on both sides of a question to resolve it in line with the requirements of the law. We look forward to continued progress in this area.

[The End]

Color Additives

By FRANKLIN D. CLARK

"Color Additive Legislation Was Very Necessary," Says the Author, and "the Amendments, as Passed, Satisfactorily Answer the Prevailing Problems. . . . the Statute Is Good Legislation, Badly Needed by Industry and Enforceable by Regulatory Officials." Mr. Clark Is Assistant to the Deputy Commissioner, Food and Drug Administration, and He Made These Remarks on November 28 at the FDA-FLI Conference.

SYNTHETIC COLORS were used in food before the original Food and Drugs Act was enacted more than 50 years ago. Some of these were known to be potentially harmful; so soon after the Food and Drugs Act of 1906 was passed, a special administrative procedure was developed by government and industry to safeguard colored food. A limited number of synthetic colors—called "coal-tar colors" because they were at that time derived from coal-tar—were selected as safe for food use provided they were pure enough. Provisions were made for batch testing of these colors by competent experts to assure freedom from harmful impurities.

The Food, Drug, and Cosmetic Act, enacted in 1938, reaffirmed the national policy of allowing synthetic colors in food, subject to safeguards considered necessary to protect the public health and prevent deception of consumers. It gave legislative sanction to the established administrative practice of listing certain colors for use in food and requiring each batch of the listed color to be tested by the Food and Drug Administration for purity before it could be marketed. The 1938 Congress had every reason to believe that even if many coal-tar colors were toxic, those which had stood the test of time were above reproach and that as additional colors were needed the procedure was adequate for their development. They added a final precaution: A coal-tar color must be "harmless" before it could be placed on the approved list. The enforcement pattern which developed was

generally acceptable to consumers, regulatory officials and regulated manufacturers alike. Ample supplies of certified colors in all necessary hues were available to satisfy the market appeal and the consumer acceptance that had become part of our way of life.

About 1950 a small cloud appeared on the horizon when a little boy became ill from eating some Halloween candy colored bright orange with an extra heavy dose of a listed and certified color. This physiological reaction to the candy was confirmed, the color itself was implicated by the process of elimination, and pharmacological testing was started on this and certain other permitted colors. It was found that by modern scientific testing methods this color was not "harmless," but in sufficient concentration was quite capable of causing harm. Similar results followed on several other colors.

Test Before Supreme Court: *Flemming v. Florida Citrus Exchange*

Here now was the problem: Could the Food and Drug Administration certify a color that was proven not harmless in relatively high concentration, even though its normal use was in amounts and in ways in which harm could not be demonstrated? Could a tolerance, either in concentration or in method of use, be established? We thought the law did not permit this and, therefore, proceeded to delist a group of colors. This action ultimately resulted in a test of our conclusions before the Supreme Court (*Flemming v. Florida Citrus Exchange*, 358 U. S. 153 (1958)). The Supreme Court unanimously agreed that the Department had properly interpreted the statute that no tolerance could be set for colors that injure test animals, and it agreed that the feeding levels employed in our tests were appropriate. If a color is a harmless substance, no further inquiry except its purity can be made about it, and it might be freely used once listed and certified. If it is not a harmless substance, no further inquiry need be made—it cannot be used at all.

Meanwhile, pharmacological testing had progressed on other permitted colors, and the evidence began to indicate that additional colors could not be tolerated for unrestricted use. About this same time it began to be abundantly clear that the 1938 Act was out-of-date in a second respect. The certification procedures cover "coal-tar" colors only, a group of colors difficult to define chemically, leaving unregulated or in the debatable "grey" area some widely used coloring

materials that for the protection of the public health should be included in a pretesting program.

From still another source came support for a change. A committee of eminent scientists, selected by the National Research Council, examined our Act as it related to colorants and concluded that a change was definitely in order. It became increasingly apparent from all sides that if coloring of foods, drugs and cosmetics was to be continued in the manner widely desired by consumers, a new procedure would have to be worked out.

A procedural trail had already been blazed by the food-additives amendment of 1958, an amendment to the Federal Food, Drug, and Cosmetic Act that provided for the inclusion, under appropriate safeguards, of chemicals that were not harmless "per se" but safe in specified amounts and under specified conditions. The Department, therefore, presented its answer to the problem in the form of proposed legislation which, after comprehensive Congressional study and some changes, was enacted and was signed into law by the President on July 12, 1960. The statute is known as the "color-additive amendments of 1960."

Basic Provisions of Amendments

The basic provisions of the amendments are:

(1) Inclusion of all coloring materials, not just coal-tar colors. Insofar as drugs are concerned, the operative provisions of the bill deal with coloring materials only if intended solely for coloring purposes, even though the basic definition of "color additive," which applies to food and cosmetic colors as well, is purposely a broad one.

(2) Authorization to the Commissioner to consider all of the proposed uses of colors, to list and certify them for particular uses, and to set tolerance limitations when needed for the protection of the public health. This safe-for-intended-use plan is similar to the philosophy embodied in the food-additives amendment.

(3) Conditioning of final admission of a color additive to the comprehensive listing, whether coal-tar or not, upon sound and adequate scientific proof that no consumer harm can result from the intended uses.

(4) Extension of the batch certification program previously applicable to coal-tar colors to all color additives not specifically

exempted by a finding that certification is not necessary for the protection of the public health.

(5) Automatic disapproval of any color which may be ingested, if the substance is found to induce cancer when ingested by man or animal, or after other tests appropriate for the evaluation of the safety of color additives. Automatic disapproval of color additives for other uses if tests relative to such uses show that the additive will induce cancer in man or animal. An *ad hoc* advisory committee procedure is included, which allows, upon petitions from interested parties or upon the Secretary's own initiative, appointment of an advisory committee of recognized experts to be selected by the National Academy of Sciences. This committee would assist the Secretary by studying, evaluating and making recommendations on the complex safety problems involving possible carcinogens in color additives.

(6) Disapproval of color additives or of specific uses of color additives that will promote deception of the consumer or otherwise result in adulteration or misbranding, or of color additives which will not achieve their intended effect within the limitations of a safe tolerance.

(7) Provisions for establishing special packaging and labeling requirements for color additives to facilitate their safe use.

(8) Authority to the Commissioner to allocate uses of a toxic color additive among the competing product demands for it, where this is necessary to provide for safe use.

(9) Provision for an interim program of provisional listing and temporary tolerances for commercially established color additives in order to permit completion of the scientific tests needed for making determinations as to the listing of the color additive under the permanent portion of the amendments. Authorization is provided to fix the temporary tolerance at a level found consistent with the protection of the public health, including, if necessary, zero levels for any color additive in use. Authority is also included to allow the Commissioner to delist a provisionally listed color if facts warrant.

Provisional Regulations

As rapidly as possible after the color-additive amendments became law and enforcement funds were obtained through action of the Congress and the Bureau of the Budget, we began working on the

provisional or transitional regulations. These were issued on October 12, 1960. They provided, pursuant to the statute, provisional lists of coal-tar colors which had been certifiable on July 11, 1960, for any use or uses under the Federal Food, Drug, and Cosmetic Act, and of which batches had been certified for such use or uses prior to the enactment date; and any non-coal-tar color additive, which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug or cosmetic. Simultaneously, the order provided for the delisting for unrestricted use of 13 coal-tar color additives which had previously been used in lipsticks and drug products. This action was made necessary by findings that when included in the diet of test animals, at pharmacologically significant levels, physiological damage was demonstrated. Through our pharmacological data, and use data submitted by manufacturers of cosmetic and drug products, we were able, however, to list these colors under tolerances which could be considered safe and which would, for the most part, allow continued use of these color additives in cosmetic and drug products at their usual level. It is important here to point out that toxicity but not carcinogenicity was involved. The order also delisted completely two external drug and cosmetic yellow colors that it had not been established could be produced without the impurity beta-naphthylamine, which is a known carcinogen.

It was realized that the provisional listing of the non-coal-tar color additives was far from being all-inclusive. The Food and Drug Administration lacked complete use data on these products and, hence, requested in the *Federal Register* that all users or manufacturers of color additives present relevant data as to prevailing levels of use of the provisionally listed color additives or of any other color additive; and to support any temporary tolerances that may be required for the protection of the public health. This data is requested prior to January 1, 1961, to be submitted to the hearing clerk of the Department of Health, Education, and Welfare. Some response to this request has been received, but we are certain that a great deal more will have to be obtained from some sources before January 1 in order to make the provisional listing complete and meaningful.

The terms of the statute provide for a 2½-year transitional period, at the end of which time it is contemplated that the color additives will be permanently listed for their specific or general use or uses, and under appropriate tolerances or restrictions, if such is necessary. There is an extremely important point that cannot be overemphasized:

At the end of the 2½-year transitional period, color additives not listed under the terms of the statute and products in which unlisted color additives are used will be illegal and subject to the sanctions of the Food, Drug, and Cosmetic Act.

It has long been apparent to the Food and Drug Administration that the amount of pharmacological work that will be necessary during the transitional period is a gigantic task. We felt it advisable to publicly meet with color additive manufacturers and users in order to appraise totally the known universe of pharmacology on color additives, and to make known to such interested parties the extent of work yet to be done. Such a meeting was held in Washington on November 17, and some of the present audience may have attended.

FDA's Pharmacological Work on Coal-Tar Color Additives

At this meeting the FDA outlined its pharmacological work on coal-tar color additives. In summary, the pharmacology on FD&C colors, insofar as food and internal drug uses are concerned, is essentially completed or in process. Insofar as the drug and cosmetic colors are concerned, none is completed. FD&C Red No. 9 and No. 10 have some chronic toxicity work; a number of others have sub-acute toxicity studies; but for the most part, the entire job remains to be done. There has been no organized work on the pharmacology of non-coal-tar color additives. There may be a great deal known about some and recorded in the literature; others may lack any scientific testing whatsoever. Each one will be a research problem of its own. The point we presented, however, was that someone would have to assemble or produce satisfactory pharmacology on all color additives and the problem was not confined to the traditional "coal-tar colors."

Amount and Financing of Pharmacological and Other Color Additive Testing

Another aim of the meeting was to resolve in some fashion the amount and possible financing of pharmacological and other color additive testing that might be done by the FDA. This point was never reached at the meeting, but we are thinking along these lines:

(1) A continuation of a fee schedule for certification of color additives for which this clearance system is deemed necessary for the protection of the public health. This would be on a cost basis, and

we would not anticipate much of a change from those charges now in effect.

(2) Establishment of a variable fee system to cover cost of permanent listing of color additives. Again this would be on a cost basis, with the fee dependent on the extent of listing requested.

(3) Finally, proposal of an actual cost system for actual pharmacological testing by the FDA. Even this would be available only up to the laboratory resources of the FDA, which would now appear to be full-scale tests on about six color additives. The main problem here would be the priority of color additives to be tested, and selection of which ones will be assumed by the FDA.

FD&C Red No. 1

One development that came about coincidently with the industry meeting was pathological evaluation of some animal test of the color additive, FD&C Red No. 1. Recent tests on this color additive have demonstrated it to be toxic to laboratory animals with the development of liver damage. On November 22 this color was eliminated from the provisional list of color additives which may be used in foods, drugs and cosmetics, because in our judgment such action is necessary to protect the public health. After publication of the order in the *Federal Register*, batches of FD&C Red No. 1 will no longer be certified and further use of this color in foods, drugs and cosmetics will be prohibited.

General regulations for the enforcement of the color-additive amendments have progressed into essentially final forms. Copies were distributed at the industry meeting. Early publication in the *Federal Register* is anticipated.

An important part of these proposed regulations which will be needed as industry shifts from the transitional into the permanent listing are the mechanics for petitioning for appropriate listings. The machinery which has worked satisfactorily in the case of food additives has been essentially adopted for the color additive regulations.

It is our belief that color additive legislation was very necessary and that the amendments, as passed, satisfactorily answer the prevailing problems. It is our opinion that the statute is good legislation, badly needed by industry and enforceable by regulatory officials. Most important, it provides the consumer with eye-appealing food, drugs and cosmetics that are safe. **[The End]**

The Federal Hazardous Substances Labeling Act

By WINTON B. RANKIN

Mr. Rankin Is Assistant to the Food and Drug Commissioner. In His Paper Before the FDA-FLI Conference in November, 1960, He Outlined the Requirements of the Law and Told How It Will Be Administered.

LAST YEAR a mother set an open bottle of furniture polish on the floor. Her one-year-old child drank part of the polish and almost died. The bottle was not labeled with any warning to the mother that it should be kept out of the reach of children, nor did it contain directions for first-aid treatment in case of injury. Another child, this time a 3½-year-old, was seriously injured from inhaling carbon tetrachloride, a liver poison, while his mother was cleaning a rug. A two-year-old was almost killed when he consumed a dishwater detergent. These are only examples of injuries that occur throughout the nation every year. The Public Health Service estimates that annually 600,000 children swallow household aids left within their reach, and about 500 of them die as a result. In addition, many adults are injured or killed each year by household substances that do not bear adequate warnings.

Similar Situation in 1920's

The situation today reminds us of the somewhat similar one that existed in the early 1920's. Ordinary lye was then a common article around the household, and many children were being killed or injured by it. The American Medical Association urged legislation to require proper labeling of this particular chemical and 11 other groups of caustic materials most frequently implicated in home accidents of that day. Many others also supported it, and in 1927 the Congress enacted the Federal Caustic Poison Act. The precautionary labeling required by that law saved many lives.

However, the law soon became obsolete. It did not apply to numerous hazardous household substances that the chemical age placed on the market. New detergents, new types of cleansing agents, various plastics, adhesives, and do-it-yourself kits—to mention only a few—were marketed after 1927 and were not subject to the old law.

There was general agreement by the doctors of the country, the manufacturing chemists, the representatives of poison control centers, consumers and the Food and Drug Administration that a modern version of the Caustic Poison Act should be developed to require adequate labeling on hazardous household substances, that would help prevent a great many of the accidents that had been occurring.

Act Patterned After Food, Drug, and Cosmetic Act

So with general support, legislation was enacted by the last Congress to accomplish this desirable goal. The act, which became law on July 12, 1960, is known as the Federal Hazardous Substances Labeling Act. In many respects it is patterned after the Federal Food, Drug, and Cosmetic Act. It prohibits the interstate shipment of a misbranded package of a hazardous substance (there are other prohibitions comparable with those in the Food, Drug, and Cosmetic Act which will not be listed specifically). It defines a hazardous substance rather specifically as any substance or mixtures of substances which (1) is toxic, (2) is corrosive, (3) is an irritant, (4) is a strong sensitizer, (5) is flammable or (6) generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness, as a result of any customary or foreseeable handling of it. (Under certain circumstances, radioactive materials may also be covered by the law.)

Definitions

These various classes of hazardous substances are further defined: A toxic substance is one that has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through body surfaces. The furniture polish that injured the year-old child last year contained a toxic substance. Additionally, there is a definition for "highly toxic" substances, and specifications are given in the law for testing to determine whether a material is highly toxic. Sodium cyanide, a chemical that has been used in some household silver polishes, is an example of a highly toxic material.

A corrosive substance is one which in contact with living tissue will cause destruction of tissue by chemical action. Muriatic acid, frequently sold in household-size containers for use in soldering and as a masonry cleaner, is a corrosive material.

Substances that are not actually corrosive but which on immediate, prolonged or repeated contact with normal living tissue will induce a local inflammatory reaction are defined as irritants. Some of the synthetic detergents sold for dishwashing and laundering are irritants within the meaning of the new law.

A strong sensitizer is a substance that causes an allergic type of reaction in some people when they come in contact with it after an initial application or sometimes after repeated use. This is not the definition given in the law, but it is an attempt to state at least a partial meaning of the definition in nontechnical terms. Before a substance is a strong sensitizer within the meaning of the law, it must be so designated by the Secretary through regulation. And in making his designation, the Secretary must find that the material has a significant potential for causing hypersensitivity. We have not yet issued a regulation designating a specific chemical as a strong sensitizer. I believe everyone would agree that if the oil from poison ivy leaves were used as an ingredient in household articles, it would be a prime candidate for classification as a strong sensitizer.

The term "flammable" is well understood. Specifications are set forth in the law for testing materials for flammability and for extreme flammability, and there is provision for the Secretary to specify appropriate tests where those specified in the law are not applicable. Benzene is flammable and gasoline extremely flammable within the definitions.

There is also provision for making the law applicable for certain radioactive substances which we find are sufficiently hazardous to require labeling.

Labels

The law requires a hazardous substance in a container intended or suitable for household use to bear a label which states conspicuously (1) the name and place of business of the manufacturer, packer, distributor or seller; (2) the common or usual name or, if there is none, the chemical name of the hazardous substance; (3) the signal word "DANGER" on substances which are extremely flammable, corrosive

or highly toxic; (4) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (5) an affirmative statement of the principal hazard or hazards, such as "flammable" where appropriate; (6) precautionary measures describing the action to be followed or avoided; (7) instructions, when necessary or appropriate, for first-aid treatment; (8) the word "poison" for any hazardous substances which are highly toxic; (9) instructions for handling and storage of packages that require special care in handling or storage; and (10) the statement "Keep out of the reach of children" or its practical equivalent.

Authorization for Secretary to Issue Regulations

The Secretary is authorized to issue regulations under the act. Among other things, he may by regulation declare a material to be a hazardous substance when he finds that it meets one of the definitions of such material. Such action will promote the objectives of the act by resolving uncertainty where there is real question as to the status of a household substance. However, we do not expect to issue a regulation listing every hazardous substance as subject to the law. In addition, the Secretary may exempt substances from compliance with the full requirements of the act to the extent he finds consistent with adequate protection of the public health and safety. Such exemptions are contemplated, for example, where the minor hazard presented by the substance does not require full compliance or where the size of the package involved makes it impracticable to comply fully.

The law provides criminal penalties, provides for seizure of misbranded packages of hazardous materials subject to federal jurisdiction, provides for injunctions to restrain violations of the act, authorizes factory inspection, and gives us authority to secure records of interstate shipments, authority to issue publicity about actions taken under the law, and authority to regulate imports.

The Hazardous Substances Act became effective upon date of enactment—July 12, 1960—but no penalty or condemnation is allowed for any violation which occurs prior to the end of the sixth calendar month after the month of enactment, that is, prior to February 1, 1961. This six-month transition period may be expanded for up to an additional 12 months with respect to specified provisions of the act or specified hazardous substances on the basis of a finding that conditions exist which necessitate such additional period.

So much for the bare outline of the requirements of the law. How are we going to administer it?

Administration of Law

We will get this law under way in much the same way as we have administered other new laws in recent years. We are recruiting staff now to work on hazardous substances. Some of our more experienced employees already are studying the over-all problem to develop educational and enforcement programs. General regulations will be drawn up under the act and published in the *Federal Register*.

We have already received some suggestions from a portion of the interested industry as to points that should be covered under the general regulations, and we will welcome advice from others who have an interest in the matter.

There is one respect in which the problem we face here is different from that which confronted us in administering other recent laws, such as the food-additives amendment or the pesticide-chemicals amendment. The earlier laws applied to firms that, with certain exceptions, were well acquainted with our procedures. But the hazardous substances laws is going to apply to numerous industries that are not familiar with the operations of the Food and Drug Administration—the paint and varnish industry, the household cleanser industry, the various industries marketing flammable materials in containers suitable for household use, to mention but three examples. These industries need to know the requirements of the new law. They need to take advantage of educational materials we develop, and their own trade groups need to develop internal educational material.

We are in the process now of establishing a hazardous substances mailing list. Any firm or association that has an interest in the new law may get its name on the mailing list by sending a request to the Division of Public Information, Food and Drug Administration, Washington 25, D. C. In this way, it will receive notices, regulations, etc., as they are issued.

In accordance with our established policy, we will implement this new law by a combination of educational and regulatory activities. We are glad to respond to inquiries from firms which would like to know whether their products are subject to the law and, if so, how they should be labeled. The following suggestions may help those

who wish comment from the FDA: The incoming letter should tell what is in the substance, and how much is present. It should enclose the labeling proposed by the manufacturer for his product, and it should contain reliable data about the hazard presented by the substance. Is it toxic? To determine the answer to this question may well require the running of an acute toxicity test to determine the LD_{50} according to the procedure outlined in the law. Is the material flammable? Is it corrosive? And so on, down the list of the types of hazards regulated by the law.

The Food and Drug Administration is not able to conduct the various tests required as a service to manufacturers. It is evident that manufacturers are themselves going to have to test their products to see where they fall under the law. As a matter of fact, a number of manufacturers say they had already done extensive testing of their formulations before the new law was enacted. But there are many small firms putting out one or a few products, which probably have not yet conducted the type of testing that will be necessary to classify their materials properly. They need to get valid information with respect to their products at an early date. Perhaps some of the industry associations serving these firms will elect to establish or contract for a central testing service that will be available to their customers. **[The End]**

PRESCRIPTION DRUG LABELING RULES CHANGED

New regulations requiring changes in labeling used to promote the sale of prescription drugs to physicians have been issued. The major labeling changes are: (1) virtually all labeling of prescription drugs (including promotional material sent to physicians) must bear complete information for professional use of the drug, including information about any hazards; (2) the quantity or proportion of all inactive ingredients must be declared on the labels of drugs for injection; (3) labels of prescription drugs must bear identifying lot or control numbers; (4) labeling bearing any information about uses and dosage must include the date of issuance or latest revision; (5) labels of eye preparations must bear the names of inactive ingredients; and (6) labels of all prescription drugs must state the quantity and proportion of the active ingredients.

Changes in new drug labeling requirements provide that permission to market a new drug may be denied if the manufacturer refuses to allow inspection of his manufacturing methods or records, and that an application may be made conditionally effective pending FDA inspection to verify the adequacy of manufacturing methods.

The changes become effective January 8, 1961, except that those parts requiring full information for use in promotions mailed to physicians will become effective March 9, 1961.

Introductory Remarks

By BERNARD L. OSER

Dr. Oser, President of Food and Drug Research Laboratories, Inc., Served as Moderator of the Industry Afternoon Session on November 28 at the 1960 Joint National Conference of the FDA and the FLI.

ON BEHALF OF THE FOOD INDUSTRIES and those related to it, I should like to express appreciation to The Food Law Institute and the Food and Drug Administration for this opportunity of hearing from representatives of the FDA and, particularly, for the opportunity of exchange in open forum with representatives of the regulated industries. We are here concerned with highly technical and complex laws and regulations, and it is important that industry's scientists and technologists, as well as its lawyers, have a clear understanding of their interpretation and significance. It is equally vital that FDA scientists have an intimate knowledge of industrial and manufacturing practices, not merely as they concern analytical and toxicological problems but also in technological respects which may be outside their present areas of specialization. These exchanges are vital to the successful achievement of the purposes of the Food, Drug, and Cosmetic Act.

I was astonished to read recently that the situation surrounding the recent inquiry (some would say "inquisition") into the personal affairs of FDA employees had deteriorated to the point where anyone making a complimentary remark about the FDA was likely to have a black mark placed against his name. At the risk of this penalty I would say from my own rather extensive professional and scientific contacts with FDA personnel, that I have never observed anything but the most impeccable conduct in their dealings with industry. Not even toward fellow scientists and associates in their own professional societies have I observed the slightest partiality in the handling of

regulatory problems. If anything, there has been a tendency to lean over backwards to avoid such bias.

As moderator of this program last year, I briefly reviewed some of the problems which then seemed to concern industry. Substantial progress has been made toward relieving the doubts and uncertainties which existed at that time. Lengthy extension lists have been promulgated, much to the relief of those concerned; and several GRAS lists have appeared, though it should be mentioned that most of the latter are still in the "proposed" state. I am sure that more GRAS lists would be welcomed by the food industries and their suppliers. It would be helpful, also, if listings of reconfirmed prior sanctions could be published—with permission, of course, of those who received them.

Progress has been made in the interpretation of the concept of zero tolerances. This is now tied to analytical methods of appropriate sensitivity. It would be a decided advantage, however, if in each case the specific method and its sensitivity were made known.

Unresolved Problems

I note that the title of this conference refers to "other unresolved problems" which, indeed, still remain. Official reluctance to apply the GRAS provisions of the statutory definition of food additives more liberally has been disappointing to many. Emphasis has been placed on the "general" degree of recognition, rather than on safety. As a consequence, insistence on the petition route has led to the filing of so-called omnibus petitions or to petitions which do not contain certain of the statutory requirements, such as reports of toxicological investigations. Some have questioned the validity of regulations which might issue as a result of such petitions.

A situation still causing some concern among analytical chemists in industry relates to the criteria of practicability of methods for controlling tolerances. It will be recalled that the difficulty of analytical methods mounts the more closely an additive resembles a natural constituent and the more minute its concentration in the food. There has been little discussion lately about the use of common v. chemical names or of the possibility of using functional labeling in lieu of either. On the subject of labeling there is still some uncertainty as to the distinction between ingredients of foods, whose presence must be declared on labels, and food additives, many of which are incidental

components. While it is not specifically an activity of the FDA, there is considerable interest on the part of industry in the development of a Food Additives Codex which would contain the specifications for the identity and purity of food grade chemicals. The proposal that the Food Protection Committee undertake the preparation of such a compendium has been under consideration, the main problem being the matter of financing this rather ambitious project.

Among the most important of the unresolved problems relating to food additives is the interpretation and application of the Delaney clause, which excludes cancer-inducing substances. The scope of the definition of cancer and the criteria for the evaluation of carcinogenic potential are under active discussion in scientific circles. There is as yet no agreement regarding appropriate dosage limitations to be used in animal studies nor on the extrapolation of the results of such studies to conditions of use by man. Among the organizations and agencies that have been exploring these questions are the Food Protection Committee (which last December issued an important scientific report on "Problems in the Evaluation of Carcinogenic Hazard from Use of Food Additives"), the President's Scientific Advisory Committee (a special panel of which submitted a report to the White House last May) and the International Union Against Cancer, which met recently in Tokyo and is expected shortly to issue its report. Next month a Joint Expert Committee of the World Health Organization and Food Agriculture Organization of the United Nations will meet in Geneva to discuss the evaluation of carcinogenic hazards of food additives. Among the questions at issue are whether a substance that induces initially a noncancerous lesion that is reversible or self-limiting should be considered a carcinogen if cancer is induced in the test animals only as a result of the excessively high or prolonged dosage under experimental conditions totally unrelated to conditions of use. One might also ask whether allegedly carcinogenic substances should be outlawed on the basis of hypothetical evidence or if only suspect, or whether the law should be literally construed—that is, that each particular substance must be found to induce cancer before it can be proscribed.

I am sure that this and other problems will be amply discussed by the speakers to follow, each of whom has not only an industrial affiliation but an association with a technical committee dealing with food additives in his or her respective fields. **[The End]**

Problems Involved with the Administration of the Food-Additives Amendment

By RICHARD S. GORDON

Dr. Gordon Addressed the Recent FDA-FLI Conference in Washington, D. C., as a Member of the Food Additives Committee of the Manufacturing Chemists' Association, Inc., and Director of Research, Agricultural Chemicals Division of the Monsanto Chemical Company.

THE 1958 FOOD-ADDITIVES AMENDMENT to the Food, Drug, and Cosmetic Act was initially heralded, at a meeting of The Food Law Institute, as a model of legislation worked out between regulatory agencies, on the one hand, and the scientists of industry and government, on the other. It was a law where the so-called rule of reason seemed to prevail in the way that petitions were to be treated and appealed. The Senate committee report at the time, for example, pointed out that a new step in law had been made, whereby the Secretary would promulgate regulations based on a fair evaluation of the record as a whole and, in the event of disagreement, the regulation might be appealed based on the same record. The basic framework of the food-additives amendment had been argued out, as you recall, over a period of more than five years, going back to the initial hearings before a select committee headed by Congressman Delaney. Every provision of the final draft as submitted to the Congress had been established as workable and fair.

However, in the last days of the session of that Congress there was added the now-famous language dealing with cancer-producing materials. Many representatives of industry and government who were consulted at the time were of the opinion that the clause was superfluous since, in fact, the Food and Drug Administration already

had the responsibility within the framework of the proposed law to ensure that such substances were not added to our food supply.

For example, the Senate report recommending passage of the food-additives amendment (H. R. 13254) stated that:

> The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

Statements by Representatives of Industry and Government

Specifically concerning the Delaney amendment, the chairman of the House committee (Mr. Harris) pointed out on the House floor that "the committee felt that the bill as reported by the committee includes the matter covered by the Delaney amendment in the general language contained in the bill." This, as I read it, is a statement that H. R. 13254 had the same meaning whether it contained the Delaney amendment or whether it did not.

The Assistant Secretary of HEW (Mr. Richardson) wrote to Chairman Harris on August 8, submitting substantially the language that we now call the Delaney Amendment, and said with respect to this statutory language that "if it would serve to allay any lingering apprehension on the part of those who desire an explicit statutory mandate on this point, the Department would interpose no objection to appropriate mention of cancer in food additives legislation." Assistant Secretary Richardson went on to say that "it would be important . . . to use language that would provide the intended safeguards without creating unintended and unnecessary complications." Again, as in the item above, the context of Assistant Secretary Richardson's letter makes it clear that HEW feels that the bill means the same thing with or without the Delaney amendment.

The Senate committee, in reporting out the legislation with the Delaney amendment, stated: "We believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration." Prior to including this statement in its report, the Senate committee conducted an informal hearing, at which the Commissioner of FDA, George Larrick, was the only witness. No transcript was made at this informal hearing, but it is clear from the Senate committee's report

that Commissioner Larrick reassured the Senate committee with respect to the FDA's views concerning the Delaney amendment.

Finally, Senator Allott of Colorado said:

> I want to go on record as favoring this legislation, the objectives of which are unquestionably desirable in eliminating the deficiencies in the present law with respect to the protection of the public health brought about by the widespread and increased use of chemicals in modern food-processing technology.
>
> I am concerned that some of the procedures established under this act may prove unworkable, and would hope that our committee and the distinguished chairman will follow the development of this program closely with a view to making any legislative corrections that appear necessary to insure its workability to deal effectively and expeditiously with the vast number of substances which will require administrative approval.

The point is, people felt that the singling out of a specific clinical event might ultimately lead to a requirement for proof of a negative (that is, the demonstration that a chemical would *not* cause cancer—something which is logically impossible). In the opinion of many scientists, this would completely vitiate the effect of the entire amendment. Therefore when, within six months of the passage of the bill, the Food and Drug Administration proceeded against organic arsenicals and stilbesterol, both of which had already been approved under the new-drug section of the act for use in animal feed, the fears of those who had originally opposed the inclusion of the Delaney language seemed justified.

Language in Amendment Leads to Arbitrary Extrapolations and Semantic Difficulties

The FDA maintained, in the case of the organic arsenicals, that since certain inorganic arsenic compounds had been reported to cause forms of cancer, further extension of the approval of these organic arsenicals could not be allowed, even though the compounds in use had been adequately tested insofar as meeting the requirements of the act. It should be pointed out that in no case have any signs of tumors or even hyperplasias been reported as a result of the chronic administration of the various organic arsenical compounds used in feeds. Several other examples of the FDA's administration of the Delaney clause seemed again to indicate that the inclusion of such language in the food-additives amendment had led to arbitrary extrapolations and semantic difficulties. One example which has disturbed many pharmacologists and biochemists in government and industry alike occurred with respect to one of the emulsifiers for use in bread.

The proposed use level of the material in question was of the order of 0.3 per cent in the bread or less than 0.05 per cent or one-twentieth per cent of the human diet. Feeding tests were carried out, and no untoward effects were observed in animals consuming a diet containing 5 per cent of the additive. (This level, you will note, represents about 100 times the level proposed for human consumption.) It was additionally noted, however, that at *25 per cent* of the animal diet, or *250 times* the proposed use in man, a metabolite of the material crystallized out of the urine causing, in approximately 16 per cent of the test animals, kidney stones or material which acted as nuclei for the formation of bladder stones. Administrative clearance for the use of the material in bread was withheld on the basis that the irritation from bladder stones can cause chronic irritation, which in turn can lead to bladder tumors, which in turn may occasionally be malignant. The problem which arises, then, is: Under these conditions, should the emulsifier be considered capable of causing cancer or should it be considered a tumorogen? At the risk of seeming to split hairs, in the case of something that may create an imbalance or an adverse physical effect where the imbalance or effect may result in a hyperplasia or even a well-defined change which in turn could lead to a nonreversible change, is the material itself rather than the imbalance or secondary physical effect to be called the carcinogenic event? Presumably, every chemical known to man can be shown to be irritating at some level and, therefore, could be considered, under one conceivable but hardly logical approach, a potential carcinogen. This brings us to a consideration of the definition of carcinogen and the practicability of establishing a threshold value for the use of a possible carcinogen in food or feed.

Definition of Carcinogen

I think you will agree that in order to define a chemical agent as a carcinogen, a scientific judgment is necessary, based on the evidence of whether or not the material is capable of directly causing a carcinogenic event under a set of specified use conditions. As a scientist working in this field, I submit that in cases where the mechanism of carcinogensis can be explained and the pharmacological conditions under which secondary or tertiary effects would or would not occur can be determined, one should have no reason to feel that the agent would be a carcinogen or that tumors could result from lower levels of administration, if the agent at the lower level does not

trigger the mechanism or create the imbalance—that is, in the case of the emulsifier, its metabolite does not crystallize out of urine to form the nuclei around which bladder stones can be organized.

In the light of the food-additives background to which I have just referred, I think the House Committee on Interstate and Foreign Commerce is certainly to be congratulated on its attempts to incorporate, within the framework of the recent color-additives bill, the provisions of the Kistiakowsky report to President Eisenhower—specifically, those provisions calling for the formation of a scientific panel to review, on request, whether or not a material is a carcinogen. However, I submit that it does not seem appropriate for scientists to have to deal with all possible extrapolations of a term which is sometimes very difficult to define. Rather, I suggest that in cases where an honest difference of opinion exists between the FDA and a given petitioner, the scientific panel should be specifically charged to assist in the evaluation of the scientific evidence appropriate to the proposed use of the chemical in question, rendering an opinion on the safety of that use without being limited only to naming a series of events as "carcinogenic." With this change in scope in mind, I should like to suggest that the concept of the advisory panel should apply to the food-additives amendment. Moreover, consideration probably should be given to extending the concept to cover all parts of the Food, Drug, and Cosmetic Act.

Concept of Scientific Panel Should Be Incorporated into Administration of Food-Additives Law

In this connection, it is a pleasure to be able to point out that the Secretary of Health, Education, and Welfare, in a speech to the Manufacturing Chemists' Association on June 10, 1960, said that he favored such an advisory committee for the food-additives amendment, responding affirmatively to the recommendation concerning establishment of such a panel as proposed by the report of the President's special commission under the leadership of Dr. Kistiakowsky.

We all recognize how difficult it would be to ask the Congress, at any time, to write legislation in the future to permit safe use at certain levels of materials that were possible carcinogens at higher levels. It might even be very difficult to establish this for secondary or indirect carcinogens—but difficult or not, we must do something *now* to implement the much-talked-about rule of reason since, at

present, the net effect is that the FDA's interpretation of the Delaney clause beclouds administration of the entire food-additives amendment by creating a climate of extrapolation and requirement for proof of a negative. As far as we in industry are concerned, we think that this problem would be alleviated by incorporating the concept of a scientific panel into the administration of the food-additives law, making it consistent with the provisions of the color-additives amendment, which was just enacted by the last Congress, but with the scope changed as mentioned above.

This panel would be concerned, broadly, with the carrying out of the recommendations of the President's special commission. Those recommendations were, as you recall, and I quote, "that it would be the function of the panel to weigh evidence and make recommendations to the Secretary on the basis of available scientific data, both on applications for approval of new food additives and in all cases where the withdrawal of a prior approval or sanction is under consideration." To continue, and paraphrasing the report slightly, the panel would also consider, among other matters, (1) whether or not the test for carcinogens is appropriate and reasonable; whether the substance is or is not, in reality, carcinogenic as determined histopathologically or by other criteria; and whether addition of the substance to agricultural products would result in a concentration of the material above the natural background level and (2) whether assay techniques would be appropriate to determine whether or not a specific carcinogen is present in food. It would also be the function of this panel to review, from time to time, its recommendations and to modify them in the light of new scientific knowledge. Further, the board would assume the responsibility of recommending to the Secretary of Health, Education, and Welfare specific research problems to be undertaken to provide this necessary scientific data. Since existing legislation does not permit the Secretary of Health, Education, and Welfare to exercise discretion consistent with the recommendations of this report, it is further recommended that the appropriate legislative changes be sought.

This last recommendation, of course, as mentioned previously, has already been provided, at least in part, in the color-additives amendment. From the people I have talked to, I would say that most scientists agree with these recommendations—and, in particular, they agree with the recommendation that specific research problems be undertaken. Most scientists also agree that the findings of the panel

should not be expected to be general or sweeping but should be, in the case of a material that is being questioned, rather specific. If experiments are to be designed to elucidate mechanism, if possible, then these experiments should lead to elucidation of the mode of toxicity and, in the case of a suspected carcinogen, whether the condition which the material imposes on the test animal is a specific and direct one, or whether it somehow creates imbalances or secondary effects which lead, in turn, to the formation of a tumor. Model experiments could well be recommended to the Secretary of Health, Education, and Welfare for work directly by the National Institutes of Health or through grants administered by the institutes.

Should Government Research in Pesticides Be Expanded?

There was one recommendation, however, with which—or with the implications of which—most industrial scientists disagreed. This was the fourth recommendation of the Kistiakowsky committee—that government research be expanded to find safer and more effective pesticides. This has already resulted in some increased appropriations to the Department of Agriculture to expand research to find "safer pesticides than are now in use." You will certainly understand that industry looks upon this recommendation with some disfavor, since it not only puts the government in direct competition with industry, which will tend to reduce the amount of industrial research which has proven so fruitful to the country in the development of new agricultural chemicals, but implies that industry itself is not bending every effort to find safer and more effective chemicals towards these same ends. What has happened, of course, as a result of the cranberry episode and of the initial actions against arsenicals, stilbesterol and emulsifiers is that the FDA's scientific and regulatory position has been taken out of context to such an extent that the public has come to feel that all chemicals are unsafe and that only a disinterested government could be trusted to find safer chemicals. It is easy to see why industry protested vigorously when this matter was actually raised in front of the subcommittee on agricultural appropriations.

My point in recounting this in such detail is that in the 2½ years since the passage of the food-additives amendment, the climate that has been produced has been such as to hamstring what was essentially an excellent piece of legislation in the public interest. I am reminded of Ben Oser's story of the old grad who returned to his alma mater

on the occasion of the fortieth reunion of his class. In a nostalgic frame of mind, he asked to sit in on one of his old classes and was surprised that they were being given the same examination he had taken 40 years before. Approaching the professor, he said: "Doc, don't you know the students must be passing these questions down from year to year? How can you hope to administer a class on this basis?" The old professor smiled knowingly and said: "Son, it's quite simple. Each year I change the answers."

We know that the problem of general legislation providing for specific cases is always difficult. Certainly we live in an era where the concept of constitutional law seems to have shifted from the concept that things not mentioned in the Constitution are the function of the state, to the opposite concept that things not mentioned as the province of the states have somehow become the concern of the federal government. I am not saying, since I don't know, whether this is good or bad. I submit it merely as a comment on our times. We also know that posting speed limits on highways does not prevent motor crashes. We know that the statistics say that five or ten people in this room will probably be severely injured or killed within the next five years as the result of automobile accidents. I don't propose to revive the tired argument that one must take hazards and that one does not, of course, have to drive a car. I also do not propose that one should have to take a calculated risk with his food supply, but we do know that a modern society has become dependent not only upon motor transportation and air travel but also on feeding people material of high quality as inexpensively as possible. We cannot go back to losing three quarters of a crop of lettuce due to the aphid or half of our cotton due to the boll weevil.

Some of us were disappointed to see in Mr. Flemming's comments to the House Interstate and Foreign Commerce Committee that, in his opinion, certain materials did not have to be used in the production of foodstuffs (I believe that he was referring to stilbesterol, to the emulsifier and to the arsenicals). Of course, the test enacted by Congress in the food-additives amendment is not whether a material is essential for its use but whether it performs, safely, the functions claimed for it, at the levels proposed. This legislation, as mentioned before, having been hailed as a major advance in administrative law, recognized the concept (in the best American tradition) of permitting a material to be found useful by tests in the market place.

Panel Should Decide Whether There Is Hazard Concerned with Proposed Use Levels of Material

I think that it is up to the panel to decide for any material, including the ones that I have mentioned today, whether or not there is a hazard concerned with the proposed use levels of the material. If we assume for the moment that the panel would find that the materials, including those mentioned, were not safe, then I think the panel should be empowered to find that it could not accept a tolerance of 0.3 per cent of a particular emulsifier in bread or a specified amount of stilbesterol in beef or chicken. But, and I stress the converse again, I do not think that if the committee feels that stilbesterol is a safe additive for beef cattle or that arsenicals are safe for poultry feed, that it should be necessary for one to have to wait for legislative action to allow their use under controlled conditions, since the findings of the panel would be based essentially on the safety to the humans consuming the foods involved.

I think there is a general agreement among scientists that one cannot set a tolerance for an active carcinogen in food to be eaten for a lifetime. The problem is, rather, that what is included by the name "carcinogen" is often difficult to define. The use of a scientific panel in this matter in conjunction with the food-additives amendment would do much to restore the climate in which the amendment was passed. It has been said that science knows very few absolutes; and with the inclusion of a panel to provide scientific review, the amendment would be quite consistent with this philosophy. Without the inclusion of the scientific panel, the absolute prohibition in the law regarding the use of substances causing cancer and the manner in which the law has been interpreted and applied by the FDA does not allow for objective review of scientific matters in terms of the perspective of human safety.

Return to Technology

I suggest that what is necessary is the return of this question to its basis in technology because arbitrary extrapolations are not scientifically reasonable. It seems unreasonable to require a manufacturer of a chemical, or the Department of Agriculture, in certifying a request to the FDA for tolerance for a material which has been found safe after suitable testing to establish first toxic expressions, to certify further that the material will not provoke other toxic responses when

used contrary to the proposed direction or at levels grossly in excess of those at which its safety had been satisfactorily demonstrated, with a wide safety margin, in the test program.

Summary

In summary, then, we would look for the speedy passage of implementing amendatory legislation to the food-additives amendment of 1958, which embodies the principles of a panel or *ad hoc* advisory board drawn from the National Academy of Sciences to review scientific matters relevant to honest differences of opinion between the FDA and a given petitioner; and, within this framework, if I may quote from the Kistiakowsky report, as read and enlarged upon by Senator Hill in his explanation of the function of the panel to the Senate during consideration of the color bill: "The panel is charged with the assistance in evaluation of scientific evidence on the basis of which decisions prohibiting or permitting the use of certain compounds, including certain compounds which may be considered possible carcinogens, might be made." Not only would this embody the President's commission's report in the law, but it would also incorporate the recommendations on the same subject made by the Department of Agriculture. It is true that the panel's authority, if drafted in the form of the Kistiakowsky report, would be somewhat different than that scope outlined by the color-additives bill, where the panel is to decide only, in our opinion, the more difficult question of semantics, whether or not a material is a cancer-producing substance. We think, fundamentally, that the scope of the panel proposed here is more consistent with the spirit of the food-additives amendment, since it provides a more objective review of public hazard in terms of how a material is to be used. Such a panel would be at least one step in the direction of a solution with which we in industry could live, and under which we could operate. It would in no way dilute or modify the Delaney language as it stands; but, rather, it would allow the Administration to establish machinery for operating under what would have the potentiality of becoming a reasonable system, and would provide a statutory basis for enabling the Secretary to make a fair evaluation of the scientific record as a whole.

Let us hope, then, that the differences which now exist between the color-additives and food-additives amendments will be speedily rectified along the lines indicated. **[The End]**

Industry's Views on the Federal Hazardous Substances Labeling Act

By JAMES D. KITTELTON

The Author Reviews Some of the Progressive Steps Which the Chemical Industry Voluntarily Took in the Field of Precautionary Labeling Before the Adoption of the Act, Lists the Basic Requirements of the Act and Discusses Some of the Questions Raised by the New Legislation. Mr. Kittelton, Who Is Secretary of the Labels and Precautionary Information Committee of the Manufacturing Chemists' Association, Inc., Presented This Paper at the FDA-FLI Conference on November 28, 1960.

THE OPPORTUNITY TO DISCUSS with you the new Federal Hazardous Substances Labeling Act is very much appreciated. This is legislation which was strongly supported by the chemical industry. It is an important law and should be of considerable benefit to the public. The labeling information required by the act will acquaint the public with the dangers inherent in certain household products and with the action to be taken or avoided to minimize the risk involved. In addition, the precautionary information should materially aid the physician called upon to treat cases of accidental injury caused by hazardous substances.

Before beginning a discussion of the new Federal Hazardous Substances Labeling Act, I would like to review for you some of the progressive steps which the chemical industry voluntarily took in the field of precautionary labeling before adoption of the act.

After the agitation for a "volatile poisons law" in the 1930's, the United States Surgeon General formed the Chemical Products Agreement Committee. The chemical industry worked closely with this committee; and as a result of this activity, several voluntary "Surgeon General's Agreements" were drawn up in 1934 and 1935. These agreements covered the precautionary labeling of methanol, carbon tetra-

chloride and a small number of other hazardous chemicals. These were voluntary agreements drawn up between the Surgeon General and the chemical manufacturers of the compounds to provide minimum precautionary labeling. They were terminated in 1952 when the Surgeon General indicated that there was no longer a need for them due to the widespread use of the labels and principles recommended by the Manufacturing Chemists' Association.

In 1936 the association stressed the importance of a voluntary program of precautionary labeling of hazardous chemicals. In that year the association sent to each member company president, a publication entitled *Confidential Report on Adequate Labeling—Its Importance to the Chemical Manufacturer.*

In 1944 the association realized that, with so many new chemical products, steps had to be taken to develop uniform principles of precautionary labeling, to foster them among chemical companies, and to recommend them to government authorities wherever the need arose. This led to the formation of the MCA Labels and Precautionary Information Committee, known as the LAPI Committee. One of its first undertakings was the preparation and publication of a manual on precautionary labeling. This is our Manual L-1, *Warning Labels, A Guide for the Preparation of Warning Labels for Hazardous Chemicals.* This booklet is intended primarily to suggest labeling for industrial chemicals. However, the general principles also have application to household and commercial products, although the specific labeling for these products may be somewhat different due to the smaller size of the container and label and different uses. The first edition of the manual was published in 1945 and is now in its fifth printing, with some 25,000 copies of the manual having been distributed to date. The LAPI Committee is now preparing the next revision and hopes to have it published soon.

Manual L-1 consists of three parts: Part I—Preparation of Warning Labels; Part II—Illustrative Warning Labels for Industrial Chemicals; and Part III—Illustrative Warning Labels for Pesticides.

Soon after publication of the manual, several states became interested in developing precautionary labeling legislation. This early legislative activity was for the most part limited to industrial chemicals. Today the States of California, Hawaii, Illinois, Massachusetts, New Jersey, New York and Oregon have regulations in effect specifying the labeling required for certain industrial chemicals. These reg-

ulations in general are consistent with the principles of precautionary labeling set out in Manual L-1.

During the past few years, as you know, major interest has turned from industrial labeling laws to those concerned with labeling of hazardous substances in containers intended or suitable for household use. A number of states have enacted such legislation or have adopted regulations. These include Colorado, Connecticut, Illinois, Indiana, Kansas, Kentucky, Massachusetts, New York, Ohio, Texas and Vermont. All of these laws and regulations are much alike, and are largely based on our MCA principles.

In addition to our own association, there are a number of others which have made substantial contributions to adequate precautionary labeling. These groups either have precautionary labeling committees or have staff personnel concerned with labeling problems. The Chemical Specialties Manufacturers Association has been especially active. It represents chemical companies in the household field, and has devoted considerable time and effort to the new Federal Hazardous Substances Labeling Act. Other groups are the American Petroleum Institute; the National Agricultural Chemicals Association; the National Paint, Varnish and Lacquer Association; and the Association of American Soap and Glycerine Producers. The American Medical Association's Committee on Toxicology also has taken an active interest in this subject.

Over the past few years, the various groups mentioned above, together with other interested ones concerned with the problem of accidental poisoning, came to the conclusion that a federal law would be desirable and would establish a uniform pattern for the labeling of hazardous household products. On January 5, 1959, a proposed model hazardous substances labeling bill was issued by the Manufacturing Chemists' Association; Chemical Specialties Manufacturers Association; the American Petroleum Institute; and the National Paint, Varnish and Lacquer Association. The bill was drafted and released after consultation with regulatory officials, physicians and other interested parties. It was consistent with the principles of labeling appearing in the MCA manual, *"Warning Labels,"* used by the chemical industry since 1945.

Soon after release of the model bill, Senator Magnuson, together with Senator Bush, introduced S. 1283 and Representative Roberts introduced H. R. 5260. These bills were identical and followed the

industry model bill. Senate Bill 1283 is the bill which ultimately became the Federal Hazardous Substances Labeling Act when it was signed by the President on July 12, 1960. It is now P. L. 86-613.

Hearings were held on the legislation by both the Senate and House Interstate and Foreign Commerce Committees. At the time of the Senate hearing, a witness for the Chemical Specialties Manufacturers Association presented certain amendments to S. 1283 which had been worked out by industry with the Food and Drug Administration. These amendments recognized the problems which the FDA would face in the administration of the law and gave the FDA some flexibility in this regard.

At both the Senate and House hearings, the proposed legislation was given strong support by the chemical industry and other interested groups. We feel that the legislation as enacted is sound and constructive, and is very much in the public interest.

I believe that it would be well at this time to review the basic requirements of the act. In addition to the name and place of business of the manufacturer or distributor, the name of the household product and adequate identification of the hazardous ingredients, the following precautionary information must appear on packages of all hazardous substances covered by the act:

(1) A signal word, such as "Danger," "Warning" or "Caution";

(2) An affirmative statement of the principal hazard or hazards, such as "Flammable," "Vapor Harmful," "Causes Burns" or "Absorbed Through Skin";

(3) Precautionary measures describing the action to be followed or avoided, such as "Keep away from heat, sparks and open flame," "Use only with adequate ventilation" or "Avoid contact with skin, eyes and clothing"; and

(4) The statement "Keep out of the reach of children."

Also in special cases, there might be required on the label first-aid treatment, the word "poison" if the hazardous substance meets the definition of "highly toxic," or instructions on handling or storing of packages which would require special care in handling or storage.

At this point I would like to discuss some of the questions raised by the new legislation. Some of these points were mentioned in the

testimony of our association before the House and Senate committees when they were considering the legislation.

We suggest that in preparing regulations under the Federal Hazardous Substances Labeling Act, the FDA carefully evaluate the existing voluntary precautionary labeling programs of the chemical industry and also the existing programs of the various states currently regulating the labeling of hazardous household products. Precautionary labels drafted according to these systems would, we believe, comply with provisions of P. L. 86-613. The point which I want to make here is the definite need for some flexibility in the wording of the labeling requirements under the new law. This flexibility could be accomplished by a provision recognizing a "practical equivalent" for any specific wording required by FDA regulations.

It also should be pointed out that a number of chemical companies will have problems concerning products which are manufactured prior to the issuance of regulations. If the precautionary information on the label of these products offers reasonable protection to the public, FDA regulations should permit existing stocks to be used before new labels or containers are required. The Secretary of Health, Education, and Welfare has the necessary authority under Section 16(b) of the act. This section permits the Secretary to prescribe a period ending not more than 18 months after the date of enactment of the act during which time there will be no penalties or condemnations.

Another point which is worthy of mention is Section 2(p)(1)(B) of the act, which requires on the label "the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard." This is required unless the Secretary by regulation permits or requires the use of the recognized generic name.

As we stated in our testimony to the Senate Interstate and Foreign Commerce Committee, we attach considerable importance to this discretionary power in the hands of the Secretary. There will be many instances where the chemical name would be very long and detailed and meaningless to the average individual and even to the average physician. It would certainly be much more useful and more informative to have a meaningful statement on the label, such as "Contains Lead Compounds" or "Corrosive Acid."

Another provision of the act which I would like to discuss is Section 11, relating to examinations and inspections. Section 11(b)(2)

of the act gives authority to employees or officers of the Department of Health, Education, and Welfare "to inspect at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, and labeling therein." In interpreting the latitude of this provision we believe that the statements made in reports of the House and Senate committee are significant. The Senate committee stated: "Inspections of unfinished hazardous substances would ordinarily be limited to those few cases where the needed information was not readily available from inspection of the finished hazardous substances." The House committee stated: "What is contemplated is such inspection as is needed to determine the composition of any hazardous substance *and* whether the labeling being applied meets the requirements of the bill." We believe that both of these statements clearly indicate the scope of the powers given to the enforcing agency under the act.

Turning now from provisions of the act itself, we would like to emphasize that proper precautionary labels are only part of the problem. A well-prepared precautionary label is, of course, utterly worthless unless the user of the product reads the label. In this connection we would like to suggest to the Food and Drug Administration that it revise its excellent booklet entitled *Read the Label on Foods, Drugs, Devices, Cosmetics,* and include a detailed section on the new Federal Hazardous Substances Labeling Act. Many of the trade associations in the household-product field also have started programs of encouraging the public to read the labels on containers of hazardous products. We believe that this activity will be expanded and accelerated.

Cooperation Between FDA and Industry

I would like to conclude this paper by stating that the Manufacturing Chemists' Association is very anxious to cooperate with the Food and Drug Administration in connection with any problems arising under the new labeling act. We believe that this is a good law, and we greatly appreciate the opportunity to work with the Food and Drug Administration concerning it. At the time of the House hearing on the act, one of the Congressmen present voiced the opinion that there had been an unusually high degree of cooperation between the Food and Drug Administration and industry on the proposed labeling act. We are confident that this cooperation between the FDA and industry will continue. **[The End]**

Impact of the New Food Law Amendment on Research in Food Technology

By MARGARET IVES

Man Always Resists Changes, but He Shows a Happy Facility to Adjust to Them Rapidly When Such Changes Occur, the Author Writes. In This Article She Points Out the Results of the New Food Law Amendment in Increased Food Technology Research. Margaret Ives, Senior Research Toxicologist in the Research Center of the American Can Company, Presented This Paper Before the FDA-FLI 1960 Meeting in Washington, D. C.

THERE HAS BEEN a lot of speculation since September, 1958, about stifled research in food technology because of the unreasonable requirements and time limits of the new food law amendment. Many remarks were quoted in the press deploring the plight of the housewife: "She will no longer be able to buy convenience foods particularly the unusual or gourmet type." "She will see no future advances in food packaging." "The price of processed foods will increase."

Two years have elapsed; and as far as we can see, none of these dire predictions has come to pass. This is usual. Man always resists changes, but shows a happy facility to adjust to them rapidly when such changes occur. Some benefit usually accrues from any change in policy, although many problems may also be generated.

The fundamental problems generated by the administration of this law to new products are twofold: (1) increased cost of development and (2) a long time interval between developmental work and commercial use because of long-term chronic testing on animals. Because this time interval may be as high as seven years and the costs

may easily be in excess of $250,000, it follows that competition may decrease since there will probably be fewer new products on the market.

There are diverse opinions among scientists as to the best solutions for these problems. The suggestions which I am making reflect my professional opinion as a toxicologist, but they do not necessarily reflect the opinions of the Institute of Food Technologists or my employer.

The immediate answer to the problem seems to be increased basic biological research, perhaps at the cellular level where rapid growth might decrease the time required to detect toxicants. This is the approach that many technical people feel should be studied. The study will take several years; thus we are back to the beginning—the costs are prohibitive. Some of the companies with large research laboratories will take the applied research approach to keep their products on the market, and devote the major proportion of their efforts to chronic feeding studies. This leaves practically no time or money to study new approaches to biological investigations. It would appear that the academic institutions will have to fill the gap.

In addition to the long observation periods required to comply with the regulations to prove safety, emphasis is also placed on the presence of trace amounts of materials in foods. Elaborate analytical techniques are often required to determine the presence of such materials in the food at the level of one part per million or less. Development of these techniques is time consuming, and requires a high degree of professional skill which cannot be assigned exclusively to food additives problems by most companies.

Enlargement of Research Programs in Food Technology

We have delineated the problems. Now, what is being done about them from a research angle? The academic institutions are enlarging their departments of food technology or pooling specialists from various departments to conduct fundamental biological research on the physiological effects of the low-level, chronic feeding. Various types of materials will be studied. The University of California has established a Pesticide Residue Research Section on the Davis Campus to study the biological effects of pesticide residues on warm-blooded animals and to develop new analytical techniques for measuring such residues. In addition, plans have been drawn up for a group to study the effects of food additives on single-cell organisms such as bacteria, yeasts and molds and on embryonic tissue. This is an attempt to

decrease the time required for chronic feeding studies. Of course, any investigation of that nature will be time consuming, since results will have to be correlated with long-term animal studies before reliance can be placed in the methods.

Purdue has established a Trace Level Research Institute for residues and metabolites. The membership of this group is drawn from many departments, and the facilities will be made available to industrial interests, such as food and fibre producers, and to the government. The institute plans to do basic research in pharmacology, toxicology, metabolism and residue problems. A similar institute exists at Syracuse University to aid the paper industry, while the Pharmacology and Toxicology Departments at the Universities of Rochester and Miami, which have engaged in this type of research for years, have widened the scope of their activities.

Stanford University has received a grant of $300,000 to study the effects of pesticide residues on man. It is their hope to develop a method for the rapid diagnosis of chronic pesticide poisoning in man. An earlier grant, which was also from the John A. Hartford Foundation, resulted in the development of an automatic analyzer for pesticide residues. The Massachusetts Institute of Technology also has plans for extending food technology research into the area of food additives. With this mention of only a few of our academic institutions which are planning to study this problem, it is apparent that they are stepping into the gap mentioned earlier.

Industry has increased its emphasis on this type of research to some degree, even though it is applied rather than fundamental research. Many suppliers of basic raw materials, who never were concerned with the uses to which their products were put, have found themselves questioned about biological activity and migration. In some fields such as steel, aluminum, resins, inks, plastic, adhesives and paper, there was no one in many of the organizations affected who was qualified to answer such questions. Several companies established animal laboratories and hired toxicologists to study their individual problems. Others hired toxicologists as consultants, and biological testing of their materials was carried on at outside consulting laboratories. These particular manufacturers probably would not have become involved in this type of work had it not been for pressure from their customers, since they did not know all the uses of their products and the significance of these uses to public health.

Food producers and packers panicked at the wording of the new amendment, and demanded unconditional guarantees of safety from suppliers. Actually, a good many of these warranties are worthless since the customer changes the material in some way after purchase in order to manufacture his product; hence, the original supplier cannot be expected to be responsible for the altered product. A material which is listed as "generally recognized as safe" or has a prior sanction is not legally a food additive and, hence, does not require a warranty if it is in the same chemical state as described in the GRAS listing or the prior sanction.

One absurd example of this situation was reported in May. A chain store required a food processor to supply them with guarantees that their food product complied with the new food law amendment. The processor decided not to take the full responsibility; he contacted the grower and demanded a guarantee from him. The grower, remembering the cranberry episode, decided to close all loopholes and demanded such a guarantee from the fertilizer salesman. The reply was: "Fertilizers are not for human consumption; they go in the ground."

Not only has biological research been stimulated in the industrial laboratories of raw material suppliers, but also the size and number of biological consulting laboratories has multiplied many times. This reflects the amount of money being spent outside of the industry's own laboratories to solve these problems.

Recently more research in government laboratories as well as government-sponsored research in academic laboratories has been directed toward the food additives problem. The United States Department of Agriculture Laboratories, especially the Western Regional Laboratory, have been quite active. The scientists in the Food and Drug Administration have also been active in the field of basic research, although their time has been limited by the great pressure of procedural and administrative work generated by the law.

Increased Emphasis on Analytical Techniques

Experts in two scientific disciplines are required to devise and apply testing procedures under the regulations of this law. The first is the toxicologist whose biological research we have been discussing, and the second is the analytical chemist. After the biological testing period is over and the material is considered a direct "food additive," a suggested tolerance with accompanying analytical test will be required in the

formal petition. The analytical chemist must develop this test. The gas chromatograph and the spectrophotometer are instruments frequently required for these analytical procedures.

In addition to direct food additives, there is also the problem of extraction from the container and, hence, indirect food additives. The problems of extractives and pesticide residues are similar, because they involve extremely small amounts of a substance and very sensitive analytical procedures. A short course on extraction procedures was held at Michigan State University in cooperation with the Beckman Instrument Company last March. This workshop was particularly valuable to those analysts, especially from industry, who were not familiar with the ramifications of the law.

Analytical laboratories in both universities and industrial concerns have acquired these newer instruments. Whereas they have been used to determine residues of pesticides, antibiotics and migratory materials, they have also been applied to other problems in food technology. Considerable progress has been made in the study of the constituents of natural products, such as the volatile components of coffee, lemon oil and vegetable flavors such as peas and cabbage. Knowledge of the composition of natural products permits the manufacture of synthetic materials with the same general properties. Often only in this way can a product be freed of a toxic natural constituent. Decaffeinated coffee is an example of such a product.

Even though the faddists would have us believe to the contrary, naturally occurring products are not *ipso facto* safe—nor even wholesome and nutritious. Rhubarb, with its extremely high level of oxalic acid, is an example of a natural product which is not completely safe. Oxalic acid is present in the leaves at toxic levels; the more moderate level in the stalk is present in an amount which reacts with the available calcium in the diet to form an insoluble oxalate so that the calcium is unavailable to the body. Such an unaltered product is not covered by the food law amendment.

Increased Emphasis on Fundamental Biological Research

Another positive gain from research, related to the food additive area, lies in the field of metabolic studies. A knowledge of the site of detoxification, metabolic end products and amount of actual tissue absorption are all necessary to assess completely the toxicity of any material. Frequently in a metabolic study one learns that the toxic

material is not the original ingested substance but a metabolic end product. Bonzer and coworkers in England have demonstrated this in the case of 2-naphthylamine.

If such a situation develops, it may be chemically possible to alter the original material so that it is metabolized by a different pathway, but maintain the desirable chemical properties. Information gained in these studies about metabolic pathways and enzyme activity is useful in other biochemical and nutritional studies.

The biochemical and pathological lesions developed in a metabolism test are clues to the outcome of a chronic test. In certain instances—but unfortunately too seldom—such a wealth of information has been acquired from the metabolic study that the long-term chronic study has not been required to clear the material.

Undue Emphasis on Trace Contaminants

Some positive and negative aspects of the influence of this law on research in food technology have been cited. Now, what is the net result of these aspects on research in general? For one thing, there has been an undue emphasis placed on trace contaminants migrating from a packaging material and on pesticide and antibiotic residues of less than one part per million.

There seems to be an advantage in using certain antibiotics which are not of therapeutic value in the preservation of food. These particular antibiotics will not cause the development of resistant strains of pathogenic bacteria. They aid in the preservation of meat in areas with poor refrigeration; they decrease the time and temperature of the heat process for canning; they are useful as a dip in preventing surface contamination of frozen meat and poultry. A test for determining the presence of an antibiotic at a level of 0.005 ppm in animal tissue has been developed. Will tolerances under the food additive law be set at such levels? Are we not straining at gnats? Also, this particular procedure points up the fallacy of prescribing a tolerance with a "practical zero" which implies zero residue when analyzed by a specific method. Such a tolerance acts almost like a challenge to the development of more sensitive methods.

Undue Concern About Dietary Carcinogens

Another negative aspect of this law is the undue concern about dietary carcinogenic activity of materials of unknown biological activity

at low levels. Attempts to prove a negative are time consuming and expensive, and the amount of scientific information obtained as a result of the necessary statistical design is meager. The American Petroleum Institute's program to prove the safety of paraffin waxes, which have been used by the American people in contact with food for several generations, is a case in point. The study has continued for several years; it has involved a great amount of animal experimentation and the services of several highly skilled scientists. Could not this money and effort better have served man if applied to the study of the causes and cure of cancer?

Effect on New Developments

Yet a third negative aspect lies in the applied research field. In the spring of 1960, one company announced it was stopping research in the field of medicated animal feeds because the work involved in determining the minute residue in the tissues and the effects of this residue on other animals and man was too time consuming and expensive. Certainly, we know that if a company cannot make a profit on an item, it cannot manufacture it.

New adjuncts, flavors, colors and packages for foods have been developed continuously by the leaders in the field. Will this rate of development continue? We hear many say "no," because they cannot afford the testing time and cost. The margin of profit in items in the food field is low. We cannot have the true answer to this question for a year or more, since many of the apparent new products today were actually in commercial use in certain areas prior to January, 1958. The question really is: Shall we have as many new food products and advancements in packaging in January, 1963, as we had in January, 1959?

Dr. R. L. Hall of McCormick and Company states: "Almost certainly in the flavor field a totally new food additive could not possibly justify the risks and expenses involved in assembling the information required in a petition. We must rely largely upon those ingredients with a history of use whether they are used intentionally as such or occur naturally in foods."

Dr. Adolph Miller of Milprint, Inc., reported in a recent talk before the Packaging Institute's recent national seminar: "Packaging costs will rise due to increased developmental costs and broadened financial responsibility given suppliers in the form of guarantees. These added costs will be reflected in rising prices of finished products to consumers.

It is obvious that the people, as represented by Congress, are prepared to accept the new costs, since the security obtained by the legislation is considered desirable."

Net Result of Impact of New Food Law

Three negative aspects have been cited which can be set against three positive ones discussed earlier. These may be stated in few words, but the impact and knowledge gained to help man are far weightier. The expanded academic research as planned at California, Purdue, Stanford and many other strong institutions will increase the basic information about the metabolism of foreign substances in the animal body. These studies may shed light on biological phenomena and advance medical research.

New analytical tools are being developed in industrial, governmental and academic laboratories, which may aid in many fields—from determining the purity of water and the atmosphere to the study of archeological relics.

The third positive aspect lies in the migration studies. Industrial polymer chemists are extensively investigating coatings, adhesives and other materials to determine what might migrate into the foods with which they are in contact. The identification of these migrants sheds light on what compounds may be formed during the curing cycles. Perhaps, further improvements of materials may result from these required tests. Who knows?

All in all, the negative aspects of this law appear to be related to human fallibility, while the positive aspects are concerned with "pushing back the frontiers of science," to quote the motto of the Gordon Research Conferences. Let us cease to be concerned with striving to perfect precise measurements of less than one part per million. Let us keep known dietary carcinogens out of our food and investigate any suspicious new materials, but not spend a fortune trying to prove a negative with an innocuous material used at extremely low levels. Let us be realistic in our judgment of food additives and not prevent the marketing of materials by demanding unnecessary and expensive testing.

If we do not strive for safety proven to infinitesimal levels but consider all the practical solutions to the problems, the new food law amendment will more than justify its existence by protecting the public health and encouraging advancement in knowledge. **[The End]**

The Scientific Advisory Committee and the Administration of Color Additives

By JOSEPH D. BECKER

The Scientific Advisory Committees Which Have Functioned in the Food and Drug Administration Reflect a Phenomenon of Modern Government, the Author Points Out in This Paper, Which He Presented Before the FDA-FLI Conference on November 28 in Washington, D. C. He Is Assistant to the Director of the Legal Department of the Allied Chemical Corporation.

PERHAPS THE MOST DISCUSSED of the 1960 color law's provisions is its Delaney clause. This provision carries forward into the administration of color additives a prohibition similar to the one on cancer-inducing additives found in the food-additives amendment of 1958. The color law's Delaney clause, briefly stated, prohibits the listing of color additives found by the Secretary to induce cancer in man or animal; his finding may be based—indeed, it is most likely to be based—on appropriate tests for the evaluation of the safety of additives.

In connection with the operation of the Delaney clause, the color law employs an *ad hoc* scientific advisory committee mechanism, an idea borrowed from the pesticide act. The advisory committee is authorized, when properly convened, to report to the Secretary on any scientific matter arising under the Delaney clause.

The advisory committee in the color law is a formal, statutory element in the administrative process. When convened by the Secretary, a petitioner or an adversely affected person, it plays an assigned role in the resolution of Delaney questions. Because the report and recommendations of the advisory committee are not binding on the Secretary, however, but merely constitute part of the data

before him, the problem of the delegation of rule-making or adjudicatory power to a private group should not arise.[1]

Points About Advisory Committee

The color law's advisory committee provision is notable in three important respects:

First, this advisory committee, unlike its cousins in the pesticide act and in early versions of the food-additives amendment, has competence with respect to the cancer issue *only*. It is not free to deal with "any question of fact" [2] raised by a petition or proposal for the listing of a color additive. Thus, in the absence of a properly raised cancer issue, questions about safety factors, analytical methods, adequacy of the testing procedure, and the like, are *not* referable to the advisory committee.

The second point to be noted about the advisory committee is that, as a matter of the statutory relationship between the advisory committee and the Delaney clause, the committee is without *formal* authority to mitigate the strict Delaney prohibition. The legislative history makes this clear. Congressman Rogers, the sponsor of the advisory committee idea, said this on the House floor:[3]

"I would like to emphasize that the provision relating the ad hoc advisory committee does not in any sense modify the effect of the Delaney clause. Cancer producing substances are unequivocally barred as in the food additives amendment. My purpose in recommending that the committee add this provision to the bill was to give added assurance to the petitioner for a color listing that his application would be reviewed by an impartial board of experts . . . ."

This means that it would be futile for the advisory committee to recommend that the Secretary list a color additive that induces cancer in man or animal because the additive is safe at low levels of ingestion.

What useful function, then, can the advisory committee serve?

This brings us to the third point about the advisory committee. While the subject-matter jurisdiction (as it were) of the color advisory

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[1] See Jaffee, "Law Making by Private Groups," 51 *Harvard Law Review* 201 (1937); *New York Evening Inquirer v. Kennedy*, 162 N. Y. S. 2d 530 (S. Ct., 1957); 1 Davis, *Administrative Law Treatise*, Sec. 603.

[2] Cf. H. R. 6747, 85th Cong., 1st Sess. (1957), Sec. 5.

[3] 106 *Congressional Record* 13321 (June 25, 1960).

committee is limited to the cancer issue and while the limits of the Delaney clause operate upon it, within these limits the advisory committee may deal with *any matter* arising under the Delaney clause "which requires the exercise of scientific judgment."[4] That is, once it is properly seized of a Delaney issue the advisory committee's jurisdiction over scientific questions is total. It may consider any and all matters toxicological, pathological, physiological or biochemical relevant to the resolution of the Delaney issue referred to it. It may engage in customary scientific inferences from data, and may deliver its scientific judgment on the basis of the probabilities or possibilities that the data suggest.

Elements of Flexibility

These very processes inherently contain elements of flexibility. After all, the foci of the committee's attention are the statutory words "induce" and "cancer." Each of those words is a vessel that does not contain, but must be filled with, meaning extracted from the data. The decision whether a result has been *induced* is fraught with considerations of remoteness, intervening or extraneous cause, and deficiencies of the experimental method. The decision that *cancer* is induced must rest on equally difficult scientific judgments. The point is that an *ad hoc* scientific advisory committee appointed from outside the government, with a broadly gauged jurisdiction over Delaney issues, is in a position to introduce an element of flexibility into the rigid Delaney system that might well be absent from official administration of the clause.

Approval of Carcinogenic Additives

Concretely, we have heard discussion of the issue whether *possibly* carcinogenic additives—that is, additives that have remote, indirect relation to malignancy—may be approved. The Kistiakowsky report regarded these additives, under a "rule of reason," as open for consideration.[5] It is here that an advisory committee might conclude, more readily than officials operating in a now sensitive area, that a given additive is possibly carcinogenic but does not induce cancer in man or animal.

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[4] Sec. 706(b)(5)(C)(i).

[5] Report of the Panel on Food Additives of the President's Science Advisory Committee, May 14, 1960, pp. 9-10

Choice of Language

It is obvious that a great deal can depend upon the choice of language in the committee's report. But a favorable report on an additive, issuing from a body of reputable scientists, would undoubtedly be given great weight by administrators. The relationship of the Atomic Energy Commission to its scientific Advisory Committee on Reactor Safeguards supports the view that such advisory committees play an important role in administrative decisions.[6] In at least four proceedings this year, the AEC was asked to take steps to approve safe sites for atomic reactors; and on the basis of the approvals of its scientific advisory committee, it did so.[7]

It is not clear from the legislative history,[8] however, whether the limitation of the color advisory committee's jurisdiction to a matter "which requires the exercise of scientific judgment" is a substantive restriction to scientific issues in contradistinction to, say, economic issues, or whether the phrase is merely a declaration that the advisory committee's job is to exercise "scientific judgment," a phrase that was a shibboleth throughout the legislative consideration of the Delaney clause.[9] Those who recall the advisory committee reports on aramite and methoxychlor will be mindful of the role that nonscientific, public policy considerations played in the conclusions of those committees. It would seem that the color additive advisory committee is cut off from these speculations by the "scientific judgment" proviso.

But the proviso does not stand as a bar to scientific commentary on the validity of the Delaney clause itself. There is a good deal of scientific opinion that thinks poorly of the Delaney clause. If that

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[6] "Although it can be argued that the approval of the ACRS is not required, even for construction permit amendments which involve the approval of design features having important safety implications, it is unlikely that the Commission would be willing to bypass the Committee on such questions." Berman and Hydeman, "Licensing Reactor Facilities," 2 *Atomic Energy Law Journal* 105, 135 (1960).

[7] Consumer Power Company (Big Rock Point, Michigan), Docket #60-5100;

Saxton Nuclear Experimental Corporation (Berks County, Pennsylvania), Docket #60-1522;

Carolina-Virginia Nuclear Power Associates (Paar, South Carolina), Docket #60-4197;

Northern States Power Corporation (Sioux Falls, South Dakota), Docket #60-4542.

[8] *See* 106 *Congressional Record* 13321 (June 25, 1960).

[9] *See* H. Rept. 1761, 86th Cong., 2d Sess. (1960), pp. 14, 89; 106 *Congressional Record* 13321 (June 25, 1960).

opinion were reflected in a series of advisory committee reports, the possibility of legislative revision of the Delaney clause would rest on a surer footing.

Criticism of Past Proposals

There has been, as you know, much criticism of past proposals for scientific advisory committees.[10] It has been pointed out that advisory committees diffuse responsibility for decision, involve unnecessary delay and, because their role is ill-defined, invite lobbying and other pressures upon their deliberations. The brief experience with the aramite and methoxychlor committees has done little to rebut these arguments. Indeed, ordinarily they would possess considerable validity. But in the context of the strict rule of the Delaney clause, any device that makes for flexibility should, I submit, be welcomed.

Reflection of Modern Government

Moreover, the scientific advisory committees that have functioned in the Food and Drug Administration reflect a phenomenon of modern government. Mention has already been made of the Atomic Energy Commission's Advisory Committee on Reactor Safeguards. Like the color additive committee, the Reactor Safeguards Committee is a statutory body drawn from nongovernment personnel, and plays an assigned role in licensing proceedings involving a safety issue.[11] A recent study has shown that, concurrently with the increasing involvement of the federal government in scientific activity, there exist 1,500 to 2,000 advisory committees which assist the federal executive in a variety of ways.[12] Scientific advisory committees advise the Department of Defense on biological and chemical warfare, they advise the National Aeronautics and Space Agency on space exploration, and they advise the Public Health Service on cancer and heart disease. It is not surprising, therefore, to find the Food and Drug Administration, a federal agency pre-eminently concerned with scientific issues, assisted by scientific advisory committees.

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[10] *See* Statement of H. Thomas Austern in *Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce (Food Additives)* (1957-1958), at pp. 216-217.

[11] 42 USCA, Sec. 2039 (1960 Supp.).

[12] *Conflict of Interest and Federal Service* (Association of the Bar of the City of New York, 1960), pp. 146, 165-179. *See Interim Report of the Antitrust Subcommittee of the Committee on the Judiciary* (House of Representatives, 84th Cong., 2d Sess.) (pursuant to H. Res. 22), April 24, 1956.

There is, however, room for improvement. The issued regulations covering pesticide advisory committees are too few to meet the criticisms that have been expressed.[13] The reports of the aramite and methoxychlor committees disclose a need for guiding standards and procedural safeguards. What is needed is a general code of fair procedures, established by regulation, governing all advisory committees that are now, or that may hereafter, function under the Food, Drug, and Cosmetic Act.

Concluding Remarks

One final point: As a result of the recent New York City Bar Association report on the federal conflict-of-interest statutes,[14] there is growing awareness of the impact of those statutes on privately employed citizens who serve on brief government assignments. The experts serving on color advisory committees will be subject to those statutes, with their criminal penalties. While there is language in the color law that exempts advisory committee members from "any other provisions of law regarding the appointment and compensation of employees of the United States," [15] there is reason to doubt that the exemption reaches the conflict-of-interest statutes.[16] Clarifying legislation is needed to assure that the issue of conflict of interest will present no obstacle to able scientists who may wish to serve on advisory committees. **[The End]**

USE OF DIRECT AND INDIRECT ADDITIVES

Seven direct and seven indirect substances may be used as additives in foods until March 6, 1961, unless regulations are issued earlier establishing tolerances or denying tolerances or exemptions from the requirement of a tolerance. The direct additives are: dimethylpolysiloxane; disodium ethylenediamine tetraacetate; kerosene (deodorized); nonylphenoxy polyethyleneoxy ethanol; petroleum sulfonate; polyglyceryl phthalate ester of coconut oil fatty acids diluted with ethylene dichloride; 1,1,1-trichloroethane.

The indirect additives include ethylenediamine tetraacetic acid, tetrasodium salt of; ethylene glycol monobutyl ether; polyamide resin; polyoxyethylated nonylphenol; polyoxyethylene-polyoxypropylene glycol block polymer; sodium dodecylbenzene sulfonate and sodium salt of naphthalene sulfonic acid condensed with formaldehyde.

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[13] 21 CFR (1960 Supp.), Secs. 120.10 and following.

[14] Work cited at footnote 12.

[15] Sec. 706(b)(5)(D).

[16] See New York City Bar Association report cited at footnote 12, at pp. 66-71, showing that exemptions from the conflict-of-interest statutes are effected by the designation of the section-number of the statutes rendered inoperative; Hoagland, "Counsel, Client and the Federal Conflict-of-Interest Laws —Part II," 6 *Practical Lawyer* 49, 51 (1960).

The Food-Additives Amendment as Related to Packaging Material

By ROBERT N. JOHNSON

The Packaging Industry Has Been Most Aggressive in Improving Foods by Better Protection, Convenience and Performance, and It Can Be Depended on to Continue in This Manner, the Author States. He Is Chief Chemist for the Processed Foods Division of The Kroger Company and Read This Paper at the FDA-FLI 1960 Washington Meeting.

THE PACKAGING INDUSTRY has done more in the way of improvement for the protection of food than any other single industry. The food-additives amendment of 1958 had greater impact on it; this is understandable, in that packaging materials had never been considered to be a food in any sense of the word.

You will recall that one year ago there was considerable confusion as to the status, programs and future of packaging materials' compliance with the law. During this past year it has mobilized itself, and now has elaborate adequate programs in all groups. It is my intent to make an inventory of the status of the various programs as they stand at this time.

It should be obvious to all that there is no individual who could possibly know all about the various clearance programs for all packaging materials. It has, therefore, been my job to contact, collect and organize information.

The number of different packaging materials is tremendous. First, I separated these into groups and subgroups, and then established in industry or in an association a specialist or expert for each; in some groups there were several. There are so many of these experts to whom I am indebted that I will not attempt to identify them.

For some groups I will give a direct quotation; in others I will indicate the apparent status based on conversations with many.

Tin Cans

This is a direct quotation with the exception that some editing has been done to remove company and individual names.

First we can dismiss the plain tinplate container because of Dr. Lehman's published statement that under normal conditions of use this type of container is safe and therefore not subject to the Amendment.

This brings us to the important problem of the interior protective coating.

As you may well know two large can manufacturing companies began working on the problem of appraising the safety of food container coatings in 1952. This included a great deal of time and effort developing methods for determining the amount and nature of can enamel extractables that could migrate to the food, and an equal amount of effort conducting appropriate feeding tests. This effort allowed the FDA and MID to issue quite a number of prior sanctions, and provided the background for the issuance of an FDA extension order in the March 17 Federal Register. In this, the FDA granted an extension of time until March 6, 1961 to a very comprehensive list of coating ingredients from which food container coatings could be made and used without jeopardizing public health, provided these coatings were made and used in accordance with good manufacturing practices. This action was taken to allow industry to gather additional data for a final order, and considered warranted because most of the coating ingredients had been in use prior to January 1, 1958 and because many of the ingredients were in coatings which had been sanctioned by the FDA and/or MID prior to the passage of the Amendment.

Following this action, Commissioner Larrick published in the April 8th Federal Register a notice of the filing of a petition by the Can Manufacturers Institute. According to this notice the petition proposed "the issuance of a regulation to provide for the use of certain substances in the formulation of organic coatings for food containers coming in direct contact with food, provided that the total addition to the food of any extractables therefrom will not exceed certain designated tolerances."

The substances proposed in the CMI petition had previously been listed as being subject to extension actions in the March 17 Federal Register and were not repeated on April 8.

At the time of the petition filing, the FDA asked that in addition to the method for determining extractables wherein the coating is applied to tinfoil and extracted in food-simulating solvents as provided in the method, that a finished container method be included which could be used in the FDA district field laboratories to patrol containers as picked-up by the district inspectors. Such a method was devised in a hurry-up fashion in order not to delay the petition filing date with the understanding that the method would be only tentative until it was checked out by collaborating industrial laboratories, and brought into its final condition. This was done and submitted to the FDA as a part of the original petition during the week of August 22, 1960. The FDA now has the completed petition and we are awaiting their action, which we hope will occur during the first 90 days, rather than the permitted second 90 days. The FDA in this action is mainly concerned with the proposed finished container test method. They are in the process of field testing the method at this moment, after which, presumably, a food container coatings regulation will be promulgated.

There are three principal parts of the petition that are of particular interest to the coatings manufacturer, the container manufacturer and the food packer;

(1) The list of ingredients from which coatings may be made is quite extensive and should cover practically all those materials (by their chemical name, and not their trade name) which are presently in use in coatings formulation.

(2) Food-simulating solvents are used as extraction liquids, thus avoiding the painful task of attempting to find a few ppm of extractables in a natural food product. Either of two methods may be used for determining whether or not the coating under consideration meets the requirements of the petition. One method, wherein the coating under test is applied to tinfoil, is intended for the coatings manufacturer, and the second, wherein the finished container, whether rigid or non-rigid is to be tested, is intended for the container manufacturer.

(3) Certain tolerances have been proposed, assignable to the general type of coating, such as one cured by oxidation with or without polymerization, and others, but in no case is the total extracts taken up by the contents of the container to exceed 50 ppm irrespective of the size or type of container or closure. These tolerances should not be difficult to meet provided the coating is made from materials on the list and in accordance with good manufacturing practices. These are only proposed tolerances and what the FDA will finally promulgate is yet to be decided. In any event, it seems certain that tolerances for the concentration of permitted coatings extractables will be set and will be realistic enough so as not to cause undue hardship to any coatings manufacturer or container manufacturer employing good manufacturing practices.

As I understand it, the regulation when published in the Federal Register will contain the complete details of the made-up container test.

It is quite apparent that the anticipated forthcoming federal regulation order will in no way change the actions already taken by the FDA in clearing coatings for manufacturers or users who have supplied formulation details, extractability data or animal feeding data to the FDA. As you well know, the FDA and MID sanctioned a number of container coatings prior to the passage of the Amendment and these sanctions can not be rescinded without proof by FDA that the coatings are hazardous. After passage of the Act and in answer to specific requests from a number of coating manufacturers the FDA provided letters of opinion to the effect they do not consider certain coatings food additives and therefore were not subject to the Act, either because under proper conditions of use, migration to food would not reasonably be expected, or that the material is one to which a prior sanction has been granted.

The anticipated FDA action in issuing a coatings regulation as requested by the CMI petition is in a manner of speaking, publishing for all to examine the criteria that the FDA has been using these past few months in providing the many letters of opinion that various coatings were acceptable for food containers.

From the overall point of view—provided of course that the FDA issues a coatings regulation—the coatings manufacturer, as well as the container manufacturer, will be required to conduct certain extraction tests under conditions somewhat in exaggeration of those encountered commercially, using food-simulating solvents in order to be sure that the coating meet FDA requirements. It seems obvious that just to use ingredients from the published list will not be sufficient, for extraction testing is an important part of the petition which probably will become a part of the regulation.

Although we are fairly confident that the much needed food container coatings regulation will be published by the FDA in advance of the March 6, 1961 deadline, the timing of FDA action, because of unforeseen extenuating circumstances which often occur in government circles, is not easy to predict, nor can the contents of the order be predicted in detail.

Now comes a question which appears to be disturbing a number of people in the packaging industry. Supposedly the issuance of a regulation will permit those in the package manufacturing industry to decide whether or not the packaging material is in compliance with the Amendment. This may suffice for a container manufacturer, but in many instances this will not satisfy the user and especially his legal staff, who will insist that a written statement be obtained from the FDA confirming the fabricator's statement that the package is in compliance with the law. Question—Will the FDA continue to review formula and extractability data and provide letters of opinion, or will the FDA because of work-load, demand that industry make these decisions?

Aluminum cans, I understand, are cleared by prior sanction.

Films

A direct quotation:

Cellophane.—*Status.*—Petitions have been prepared and delivered to FDA requesting regulation on the food additive ingredients in all cellophane films sold for food packaging. All have now been accepted for filing by the FDA.

Pending publication by FDA of a formal regulation, these films are being sold for food packaging in compliance with the Food Additive Amendment of 1958 under extensions granted by the FDA.

Program.—Petitions were prepared to reveal to the FDA information on the amount and safety status of all film ingredients. On each food additive ingredient detailed information was included on the function, safety, extractability, and methodology to support requests for regulation by FDA.

In several instances, FDA requested and was furnished supplementary information before final acceptance for filing.

Progress.—Based on the close cooperation with the FDA in the preparation of the petitions, we confidently expect that the petitions as filed furnish sound bases for favorable action by the FDA.

"Mylar" Polyester Film.—*Status.*—"Mylar" base films and polymer coatings as applied on the M-22 heat sealing type are not food additives within the meaning of the Food Additives Amendment of 1958. Their use for food packaging was sanctioned by both the FDA and the Meat Inspection Division of USDA prior to the Act. The prior sanction coverage limits package exposure temperatures to 250° Fahrenheit, maximum.

Program.—Information has been furnished to the FDA on all coated "Mylar" films to confirm the "prior sanction" status. Further action will be taken if and as required by FDA.

Polyethylene.—*Status.*—A petition covering polyethylene resin, including the film form, requesting regulation for its safe use in all food packaging has been accepted for filing by the FDA. Pending FDA action on the petition, polyethylene films are being sold for food packaging in compliance with the Food Additives Amendment of 1958 under extension granted by the FDA.

Program.—Industry programs to clear polyethylene for packaging all foods have been conducted in close cooperation with the FDA. Development of the petition has been in the form indicated by FDA to be satisfactory.

Progress.—Polyethylene suppliers are awaiting FDA action on the petition.

It is my understanding that Saran and Pliofilm are both cleared by prior sanction.

One film—polyproplyene—has been approved by regulation.

Glass and Closures

As to glass containers, it has been demonstrated that there is no migration and, therefore, they are not subject to the law. Abrasion-resistant coatings are sometimes used on glass; at present, there are both approved and unapproved coatings for this use.

As to closures, the facings are essentially the same as the approximately 300 can interior coatings which are extended and the clearance of which is being programmed by the tin can manufacturers, as mentioned in my comments on that material.

Adhesives

This again is a direct quotation:

(1) **Status.**—The Adhesives Manufacturers Association has contracted with Syracuse University Research Corporation to run migration tests on adhesives for (a) dry food packaging, (b) aqueous packaging, and (c) fatty food packaging. The studies on dry food packaging have been completed and a petition covering adhesives for dry food packaging has been filed and accepted by FDA. Migration studies at Syracuse on aqueous and fatty food packaging are in progress, but have run into some unexpected delays indicating that appropriate petitions will not be ready for filing until 1961.

(2) **Problem Areas.**—There were many diverse problems connected with an industry-wide program such as this, but primarily the two major problems were (a) setting up detailed migration study procedures at Syracuse, and (b) gathering and correctly identifying the more than 700 ingredients used in adhesives for food packaging.

(3) **Program for Compliance.**—Because of the indicated complexity and difficulties in clearing more than 700 items, it was mandatory that a simple reliable approach be made. Following conferences with both the technical and administrative divisions of FDA, the so-called "omnibus petition" principle was adopted, under which the migration results from these tests would safely clear most, if not all, ingredients in adhesives.

(4) **Anticipated Results.**—It is too soon to say, but based on progress made so far and based on informal conversations between Industry and FDA the adhesive industry is optimistic.

Paper and Paperboard

I discussed this packaging material with a large number of individuals working actively with it.

At the present time, all the ingredients and components of paper and paperboard are being used either because it has been determined exempt or is under a time-extension. It is optimistically expected that this latter group will become exempt or will become approved covered by regulation.

For many years, suppliers of major components such as starches and rosen sizes have been conducting programs. Since the enactment of the law, trade associations—notably, the American Paper and Pulp Association and National Paperboard Association—have developed programs for compliance. Of interest are three:

(1) Extraction tests using chocolate, bacon and lean meat, being conducted by the Hazelton Laboratory. (2) Analyses for heavy metals including lead, mercury, etc., being conducted by Syracuse University. (3) Abrasion tests using sand and salt, being conducted by the Institute of Paper Chemistry.

It is expected that the data from these tests will be submitted to the Food and Drug Administration in late November or early December.

Waxes

We all know that the American Petroleum Institute has been working diligently for several years on a clearance program for waxes. This has been done in conjunction with, and is considered adequate for, the FDA. Reports are optimistic. The primary problem at the moment is the development of quality control methods satisfactory to the FDA.

Summary

There is general optimism regarding the progress and eventual results of the various programs for compliance with the law of present packaging material. On the other hand, there is a very definite negative note as to the effect of the law on research and development of new materials. It is felt that companies will be reluctant to develop new materials, recognizing that in addition to research, development and marketing costs there will also be the added cost in money and time to obtain proof of safety; and, of course, this is not assured.

As mentioned earlier, the packaging industry has been most aggressive in improving foods by better protection, convenience and performance, and can be depended on to continue in this manner.

[The End]

Additive Labeling

By B. E. ELLICKSON

The Author Discusses the Use of Identified Functional Names for Many of the Additives Used to Improve the Quality and Taste of Food Products. Mr. Ellickson of the National Dairy Products Corporation Presented This Paper in November Before the FDA-FLI National Conference.

BEFORE I GET INTO THE MAIN SUBJECT of this paper, which is concerned with the problem of chemical names on food product labels, I would like to take this opportunity to compliment our Food and Drug Administration on the excellent job they are doing in their Herculean task of discharging their responsibilities to both the consuming public and the various members of the food and allied industries. While many of our Food and Drug people are here this afternoon, my compliments are also extended to all of the others who are back in the offices and laboratories "minding the store."

Recognition of Act's Importance

I am sure that while there are many areas of disagreement between the public, the government and industry, we can all agree upon the basic importance of the Food, Drug, and Cosmetic Act with its necessary amendments. The disagreements are not basic but are more often disagreements in viewpoint and interpretation which, as time goes by, are resolved by discussion, enlightenment and reasonable compromise.

Most of the members of the food industry have a high regard for food and drug law, and have considered this law important and necessary. We in this room, I am sure, are all aware of the fact that the food industry was actively behind the food-additives amendment, and recognizing a need for a change in the Act, heartily endorsed a change. I am equally certain that most of the members of the food

industry took action similar to that of my company. As early as October, 1958, our management discussed the then recently enacted amendment and determined a policy for meeting the problems and establishing the methods by which they would be certain that they could continue in compliance with the law.

Recognition of Problems

Of course many problems have arisen, have been met and resolved. Other problems still exist, but these, too, are being met and will be resolved. These problems have legal, scientific and practical aspects. Our law says we must label products listing all the ingredients contained in the product we sell to the consumer. Corporation counsel advises us how best to meet the requirements of the law in this regard. As scientists we know that milk, for example, contains in minute amounts, many chemicals put there by nature. These are not added in the industry processing plant—they are there as the milk leaves the cow. Undoubtedly the cow is not yet aware of the food-additives amendment and the need for compliance. Fortunately, the Food, Drug, and Cosmetic Act and the food-additives amendment are more concerned with the things man might add to milk than with what the cow puts in her milk. If we add Vitamin A and Vitamin D to the milk —that we put on the label. Here again, we are fortunate that vitamins are commonly recognized by that important element of the food industry usually referred to as the "consumer." Thus we have a common or usual name—Vitamin A_1. The chemical name of Vitamin A_1 is "3,7 dimethyl 9-(2,6,6-trimethyl-1-cyclohexen-1-yl)2-4,6,8 nontetraen-1-ol." From the viewpoint of a milk processor, it would be highly impractical to list this long, complicated chemical designation. Not even all chemists would necessarily know what this compound was. Imagine the consternation with which the housewife would view a bottle of milk saying "3,7 dimethyl 9-(2,6,6-trimethyl-1-cyclohexen-1-yl)2-4,6,8 nontetraen-1-ol added."

Common or Usual Name

The law, of course, only requires that the "common or usual name" be used. Vitamin A_1 has another name. That name is "retinol." This is a nice, short, brief name—but, if we did not already have the common or usual name, Vitamin A_1, we wonder how enlightened the housewife would be if she read "retinol added" on a bottle of milk.

Here we find ourselves faced with some of the problems in labeling. I have chosen Vitamin A_1 because I am reasonably certain that everyone in this room has heard of Vitamin A.

A case in point is the labeling of nonstandardized salad dressings containing EDTA. Under the present food additive regulation, a salad dressing containing this chemical must be labeled "calcium disodium ethylenediaminetetracetate" or the proposed common name "calcium disodium EDTA" followed by the chemical name "calcium disodium ethylenediaminetetracetate" in parentheses.

I know of at least one food company which, for several years previous to the food-additives amendment, attempted to alert the public to EDTA by labeling two of its products which contained EDTA as "disodium ethylenediaminetetracetate," followed by EDTA in parentheses as a preservative. These products, of course, were nationally distributed and enjoyed a large volume of sales. Representatives of this company, at least, feel that the public has encountered EDTA to a large enough degree to permit labeling merely as EDTA or, at least, calcium EDTA.

We in the food industry are very much aware of the problems of labeling our products in such a manner that the consumer is fully informed. We are also quite sure that deciding what a "common or usual name" for a substance is that will receive general recognition at the consumer level is far from a simple task.

Solutions for Problem

Commissioner Larrick on at least one occasion—September, 1958, in addressing the Association of Official Agricultural Chemists in Chicago—informed us that the FDA is well aware of this problem. We agree with the Commissioner that the consumer has a right to know what is in his food, and we have no objections to the fact that the law provides the consumer with this right. In the same speech. Mr. Larrick suggested a means of resolving this problem. He suggested (1) that an industry committee be set up on nomenclature or that some other mechanism be put into effect to agree upon synonyms for chemical names and (2) that the synonyms adopted be understood by all and receive official recognition. As Mr. Larrick indicated, this has been done for pesticides. For pesticides, this is a somewhat simpler task. The pesticide manufacturers are chemists dealing in a

specialized field and, for the most part, belong to a single association with a mechanism established for handling this problem. Perhaps Mr. Larrick's suggestion should be followed, but to date the many factions of the enormous food industry have no practical method for arriving at this happy solution.

Use of Functional Names

The food law bar has suggested that the FDA permit the use of identified functional names for additives. If this were possible one could, presumably, label the nonstandardized salad dressings "EDTA" or "Calcium EDTA, a chelating agent added." Perhaps the consumer would not immediately know what a chelating agent is, but a really curious consumer could find a definition for chelate in a Webster's unabridged dictionary.

This same curious consumer will have a somewhat more difficult time with calcium disodium ethylenediaminetetracetate—which, unless he is in possession of certain specific chemical knowledge, means nothing to him and might even worry him. After all, he has been told chemicals are being added to his food and this proves it.

If our curious consumer is also intelligent—and he often is—he might even suspect that the reason for adding a chelating agent is to give him a better quality product which is more uniform and more stable, and keeps better—not only on the grocer's shelf but in his own home as well.

Conclusion

In conclusion, I would like to say that these remarks are only intended to recall to our awareness that in the realm of labeling food additives there are problems yet to be resolved. These problems can be resolved if the food industry will make a strong effort to reach agreement with the Food and Drug Administration on a reasonable method of informing the public of the additives in their foods. They will be resolved if the Food and Drug Administration will also consider the alternative of identified functional names, since common or usual names do not seem to exist for many of the additives which permit us to bring more nutritional, higher quality, better tasting, safer food products to the consumer. **[The End]**

Recent European Food Law Developments

By FRANKLIN M. DEPEW

Mr. Depew Reports on His Recent European Tour, Which Came About upon an Invitation to Attend the British Pure Food Centenary in London as Vice President of Honour. He Is President of The Food Law Institute.

I RECENTLY ENJOYED a most rewarding and stimulating series of visits with a number of food and drug officials of international organizations and of European countries. The opportunity to make these visits came about when I accepted the invitation to attend, as vice president of honour, the British Pure Food Centenary in London, which celebrated the General Pure Food Act of 1860. This important event has been fully reported in the November, 1960 issue of the FOOD DRUG COSMETIC LAW JOURNAL, which was devoted to the centenary.

French Food Law

At the conclusion of the centenary I went to Paris, where I discussed food law developments with Mr. Henry F. Dupont, secretary general of the *Commission Internationale des Industries Agricoles* (CIIA) and Mr. Louis de Saint-Rat, laboratory director of the *Bureau International Permanent de Chimie Analytique* (BIPCA).

The CIIA was established by intergovernmental agreement in 1934 to study scientific, technical and economic questions affecting the food, agricultural and biological industries; to act as an international information center; and to arrange international meetings and exhibitions. The total membership of the CIIA consists of 41 nations, including the United States. The CIIA acts as the secretariat of the Council for the European Food Code.

The BIPCA was established by intergovernmental agreement in 1912 to further comparison of analytical methods, to see what common steps might be taken to prevent adulteration and to facilitate international exchanges. It has eight member nations.

Messrs. Dupont and de Saint-Rat advised that they did not expect any revisions in the French food law in the near future. Both were of the opinion that the diets of Europeans were so different from those of Americans that the problems of safety of "food additives" must be viewed on an entirely different basis in each locality. The fact that a substance was found to be safe for use under the conditions existing in the United States would not necessarily make it safe for use in Europe, in their judgment, because of these differences in eating habits. However, they felt most substances could probably be agreed upon as internationally acceptable.

Both also expressed the view that the progress of the European Food Code would be slow and that the draft of the language of the code would not be completed for several years. In the meantime they favored trying to secure international agreements for minimum standards for basic foods. This program is already under way at the FAO.

I also met in Paris with Mr. M. Toubeau, director, *Service des Repressions des Fraudes.* This agency enforces the French food law as well as many other laws involving possible deceit of the public. Mr. Toubeau told me that no change was contemplated in the French law unless the Common Market countries reached some new agreement which would be binding on France as a member.

During our stay in Paris, Dr. Dupont was kind enough to entertain Mrs. Depew and me at his club, the *Circle Interallie.* We had a most delightful luncheon with Madame Dupont, Mr. de Saint-Rat, Mr. Paul G. Minneman, who is agricultural attaché at the United States Embassy, and Mrs. Minneman.

German Food Law

In Germany, Dr. Walter Kraak, president of the *Bund fur Lebensmittelrecht und Lebensmittelkunde* (Association for Food Law and Food Science), most kindly arranged a meeting and luncheon with his associates and Mr. Edmund Forschbach, deputy ministerial director of the German Federal Ministry of the Interior. This took place at

the Petersburg Hotel in Bad Godesberg, located on a mountain top overlooking the Rhine, across the river from Bonn. The view was magnificent and included some of the ruins of old castles of the Rhine barons on the adjoining hills, as well as the valley of the Rhine.

Two Categories Under Law

It was pointed out that the new German food law is unique in that it defines *fremdstoffe* (foreign substance) basically to be any substance which does not contain digestible material. It was further pointed out that, in addition, the basic philosophy of the law in respect to foreign substances was changed by the law from "Everything is permitted unless it is expressly prohibited" to "Everything is prohibited unless it is expressly permitted." The view was expressed that these two factors had led to many more substances being brought under the restrictions than had been the intention of the legislators. Mr. Forschbach stated that the substances for which permissions may be granted under the new law can be grouped in two categories:

(1) substances which are covered by the term "foreign substances" and which are completely harmless (plain water, for instance, which has already been exempted by the law itself), and

(2) substances which for reasons of public health may merely be tolerated (in particular, this group includes certain preservatives and colorants).

This distinction is not explicitly set forth in the law, but it was Mr. Forschbach's opinion that a proper interpretation of the law permits it.

European Food Code

Mr. Forschbach then discussed the European Food Code and stated that he felt good progress was being made with regard to the basic plan to be presented at the next general meeting of the Council for the European Food Code. However, he did not expect the draft text of the code to be completed before late 1962 or early 1963. When the text is finally agreed upon, the council will then be able to recommend it to the individual countries for consideration and possible adoption, either by treaty or by legislative enactment. Mr. Forschbach reported that among the major food code problems recently solved

was that of cooperation with the international organizations, World Health Organization (WHO) and the Food and Agricultural Organization (FAO) of the United Nations, for which a joint committee will be established.

Mr. Forschbach felt that uniformity of the food laws within the European Common Market would make more rapid progress, as the Council of Ministers of the Common Market has the power to bind the member countries. He regretted that Great Britain, which is not a member of the European Common Market, has not participated in the work for the European code. He felt that there were no great discrepancies between those countries in their views concerning food laws, and said there was a chance that Great Britain might soon join the preparatory work for the code. I shared his hope that this might be the case.

Vienna

On our arrival in Vienna we were entertained at the home of Mr. and Mrs. Wolfgang Tursky. This home, which had been occupied by the Russians during the war, still retained its delightful old Viennese atmosphere. After dinner we adjourned to a charming old wine cellar in their house; the walls were of the original pale terra cotta brick curving in toward the ceiling. A bar had been added as a bow to the present, but the room was furnished with pieces belonging to the family since the Renaissance. The evening passed all too quickly with pleasant company, good talk and the sipping of new wine. Among the guests were Dr. Hans Frenzel, president of the Council for the European Code; Dr. Karl Gruber, former Austrian Ambassador to the United States; Chief Councillor Paul Fanowitz, Professor Dr. Schindl; and their wives. This delightful occasion gave us an opportunity to become acquainted on an informal basis.

The next day Dr. Frenzel was kind enough to give me an English translation of the Provisional Statutes and Rules of Procedure of the Council for the European Code. Dr. Frenzel reported that Mr. F. H. Townshend of the FAO had visited him the week before and that it looked as though the council and the FAO might work together in furthering the adoption of the code. While we were in Vienna, we saw "Don Giovanni" and "Madame Butterfly" at the newly renovated Vienna Opera House, as the guests of Drs. Frenzel and Fanowitz. These two delightful evenings will be long remembered.

Rome

In Rome I visited Dr. Norman C. Wright, deputy director of the FAO; Mr. F. H. Townshend, legal research officer; Dr. N. Autret; and others in the Nutrition Division. At the time of my visit a European regional conference was in progress, and the delegates gave consideration to the problem of cooperation with the council for the Code. The conclusion reached has not as yet been disclosed.

In the event the reader is not familiar with FAO publications, he will be interested to learn that the organization publishes a report, from time to time, on current food additive legislation. Its cost is $6 per year. This service, as well as other FAO reports relative to current developments in the international food field, may be purchased through the Columbia University Press, 2960 Broadway, New York 27, New York.

Geneva

In Geneva I visited with Dr. Robert C. Burgess, chief of the Nutrition Division of the WHO, and with members of his staff. They cooperate with the FAO with respect to the food standards program and in reporting food additive developments.

Everyone at the FAO and WHO seemed most interested in the work of The Food Law Institute and in cooperating with the institute in fostering uniform foods laws which eliminate trade barriers.

Summary of Trip

I would sum up my impressions from this trip by saying that my discussions with these officials confirmed previous indications that there is widespread interest in a modernizing revision of the local food laws of many European countries. All these prominent food officials whom I visited regard this as desirable in order to protect the consumer's health, to assure high quality and to eliminate objectionable trade barriers. On the other hand, those branches of the food business which benefit from these economic barriers cannot be expected to look with favor upon their removal. In addition, we cannot overlook the possibility that this movement for new food legislation will be misused for political purposes. It is important that the FLI cooperate with these officials and their organizations in emphasizing the basic desirability of sound, uniform legislation.

I am confident that the representatives of the European Council for the Codex, the FAO and WHO, etc., will welcome the efforts of The Food Law Institute in furthering this mutually desirable goal.

Mr. Townshend of the FAO has since written me to graciously advise that he will be at our disposal with reference to any recommendations we may wish to make relative to developments in the future, including such matters as uniform food laws. Recently, I was most gratified to receive from Dr. Frenzel, in behalf of the council, a note of congratulations and an offer of collaboration reading as follows:

> President Depew had the kindness to inform me that your very esteemed Institute will hold a great celebration at the end of November of this year. The European Council for the Codex Alimentarius has authorized me to congratulate you upon this occasion. The excellent publications issued by your Institute are well known and very much appreciated throughout Europe. I am convinced that the European Council for the Codex Alimentarius will derive great advantage from our mutual contacts and I shall feel very much honored by our collaboration. With the best wishes for the future and most kindly regards.

The institute will continue to work with these organizations and will keep its members informed of any developments, so that they may make suggestions.

I cannot close without expressing thanks for the many kindnesses extended to us on our trip. They were most gratifying as a reflection of the interest and esteem with which the FLI is viewed. **[The End]**

WASHINGTON—ACTION AND NEWS—

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originator of the Hoxsey treatment, as the Hoxsey Clinic. Thousands of cancer patients came to the clinic from all parts of the United States and other countries. Cancer patients are estimated to have spent over $50 million for the Hoxsey treatment since its inception.

Use of External D & C Red No. 15.—On January 10, 1961, John L. Harvey, Deputy Commissioner of Food and Drugs, signed an order permitting the use in externally applied drugs and cosmetics of the color formerly known as FD&C Red No. 1, a water soluble coal-tar color. For this use, the color will be designated as External D&C Red No. 15.

The action modifies an order of November 26, 1960, eliminating all use of FD&C Red No. 1 because preliminary experiments showed that the color produces liver damage when fed to test animals and that no safe level has been established for internal use. The FDA immediately discontinued certification of any further batches of this color—then widely used in a variety

of foods as well as drugs and cosmetics but not in lipsticks—and cancelled outstanding certificates for all previously certified lots.

Subsequently, the Toilet Goods Association and others petitioned for provisionally relisting this color additive for use in externally applied drugs and cosmetics.

Commenting on the action of January 10, Mr. Harvey said: "The pharmacological studies on which the delisting order (of November 26) was based involved the ingestion of the color additive in the daily diet of test animals. From the facts now before us it is found the protection of the public health does not require the continued prohibition against using this color additive in externally applied drugs and cosmetics."

Certificates previously issued for FD&C Red No. 1 and canceled last year may, upon appropriate application, be reissued to cover the limited usage as External D&C Red No. 15.

The feeding studies are being continued for the purpose of resolving the question of whether the additive may be capable of causing cancer. However, the FDA said this is not a problem with the external use of the color.

FDA Will Have Consolidated Washington Headquarters and Laboratory in 1963.—Ground has been broken for a modern $12,212,800 building which for the first time will provide a consolidated headquarters and laboratory for most of the Food and Drug Administration's Washington operations.

The General Services Administration awarded a contract for construction of the six-story, plus basement and subbasement, structure to J. W. Bateson Company, Inc., of Dallas, Texas.

It is scheduled to be completed in March, 1963. Six months before the completion date, installation of an estimated $7 million worth of equipment will begin. This work will be completed six months later, but a considerable portion of the FDA's 805 Washington employees scattered in five separate locations will already have moved into the structure.

The building will be concrete with limestone facing and aluminum spandrel windows.

The FDA's present space is inadequate and antiquated. Dispersion of present space has required separating organizational units. Some bureaus have units in as many as three different locations separated by distances of from one block to three miles. Transportation and communication costs are excessive.

The FDA also is in the midst of a long-range expansion program which has been carried on by annual increases in appropriations since 1956. Authorized budget increases provide for a field staff which far outnumbers headquarters personnel.

Without additional headquarters personnel and space, however, the FDA would be unable to continue its expansion. Lack of space in Washington is already a limiting factor in the FDA consumer protection programs throughout the country.

Location of the building in Southwest Washington is an expansion of the Department of Health, Education, and Welfare complex there. The North HEW building, in which the FDA now has 26,754 square feet of space, will be diagonally across Third Street. The FDA building also will be in line across Third Street from the South HEW building and a tunnel will connect them.

Here are a few of the features of the building:

There will be 300,000 square feet of assignable space. The FDA now occupies 185,469 square feet, the largest portion being cramped laboratories first occupied in 1936 when the FDA was in the Department of Agriculture.

The laboratory areas will be on all six floors. For the first time, there will

be central storage for such things as chemicals and glassware, with central washing facilities and a central media plant.

A special chromatographic room for the Division of Cosmetics will be two stories high.

The entire building is so designed that it could be converted entirely to laboratory work.

The FDA's scattered scientific material, gained through years of experimental work, will be consolidated in a 7,000-square-foot library.

A permanent exhibit room will be located on the first floor.

Dallas District Staff Assignments.—Major staff assignments for the new Eighteenth District of the Food and Drug Administration in Dallas, Texas, have been announced by George P. Larrick, Commissioner of Food and Drugs.

The establishment of the new district as a centrally located field headquarters in Texas and Oklahoma makes possible improved service to consumers and industry in these and adjoining states, Mr. Larrick said.

Sam D. Fine, of Columbia, Missouri, the new director, has directed the Kansas City District since March, 1957, and prior to that was chief chemist at the Denver District. At Dallas, he will supervise a staff of 83, including scientifically trained inspectors, analytical chemists and administrative personnel. Mr. Fine began his FDA career in 1939 as a chemist at St. Louis. He received his education at Southeastern Missouri State Teachers College (B. S. in Education) and at the University of Missouri (M. A. in Education, specializing in mathematics and chemistry).

Alfred Barnard succeeds Mr. Fine as director of the Kansas City District. Born in New York City, Mr. Barnard was educated at Rensselaer Polytechnic Institute, Georgia Institute of Technology and the University of North Carolina. He began his FDA career in 1941 as an inspector at the Atlanta District, and subsequently has held increasingly responsible assignments as an inspector at the Baltimore District, resident inspector for the District of Columbia, food and drug officer in the Bureau of Field Administration, Washington, D. C., and chief inspector of the San Francisco District.

Three other officials in the Dallas District named by Mr. Larrick were:

Chief Inspector.—Named to this position was James E. Anderson of Fargo, North Dakota, who obtained his Bachelor of Science degree at North Dakota State College and began work as a seafood inspector with FDA in 1942 in New Orleans. After serving as an inspector at Minneapolis and resident inspector at Omaha, Nebraska, Mr. Anderson has been the Kansas City District's food and drug officer.

Chief Chemist.—Norman E. Foster of West Collingswood, New Jersey, will be in charge of the modern district laboratories staffed and equipped to make chemical, bacteriological, microanalytical and microscopic analysis of foods, drugs and cosmetics. Mr. Foster obtained B. S. degrees in Pharmacy and Chemistry at the Philadelphia College of Pharmacy and Science and at the Alabama Polytechnic Institute, and began work with the FDA in 1938. He has had experience in both scientific and administrative phases of the FDA's enforcement programs at the Philadelphia and Minneapolis Districts.

Food and Drug Officer.—William C. Hill of Anna, Illinois, will conduct interviews and formal hearings with industry members and assist in work planning and obtaining evidence of law violations. Mr. Hill received his B. S. in Education at Southern Illinois University, Carbondale, Illinois, and has had experience since 1948 at the St. Louis and San Francisco Districts as inspector and food and drug officer.

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